

# GLOBALIZATION AND ACCESS TO DRUGS

## PERSPECTIVES ON THE WTO/TRIPS AGREEMENT

Health Economics and Drugs

DAP Series No. 7

*Revised*



World Health Organization  
Action Programme on Essential Drugs

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World Health Organization

WHO/DAP/98.9  
Original: French  
Distribution: General  
Revised

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# Acknowledgements

The authors acknowledge the following individuals who contributed comments and constructive suggestions to the review of this document: D. G. Barboza (Law Firm of Neviani, Borges & Beildeck, Rio de Janeiro); P. Chirac (pharmacist, la revue Prescrire, Paris); C. Correa (Professor at the University of Buenos Aires); M. Haubert (Director of the Institute of Study on Economic and Social Development at the University of Paris I); B. Remiche (Professor at the University of Louvain); as well as F.S. Antezana (Former Deputy Director-General, WHO), and P. Brudon, D. Fresle, H.V. Hogerzeil, J.D. Quick and T. Sodogandji, from the Action Programme on Essential Drugs, WHO.

The authors acknowledge the helpful comments and clarifications received from the Secretariat of the World Trade Organization.

The interest expressed by Member States, multilateral organizations and nongovernmental organizations (NGOs) is also acknowledged.

## Note to the reader

This document represents an introduction to the issue and one of many contributions to the on-going process of analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements. The main text of this revised version of *Globalization and access to drugs* incorporates the helpful comments and clarifications received from the Secretariat of the World Trade Organization. The views expressed are solely the responsibility of the authors as with all WHO documents by named authors. This revision also contains speeches which were presented at the WHO Executive Board ad hoc working group on the Revised Drug Strategy, held in Geneva on 13 October 1998. The section on definitions and terminology has been updated. The bibliography and other reference material remain as in the original.

First edition November 1997  
Second edition January 1999

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## Abbreviations and acronyms

ACP	African, Caribbean and Pacific Group (Lomé Convention)
ASEAN	Association of South-East Asian Nations
DAP	Action Programme on Essential Drugs
DC	Developing countries
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSP	Generalized System of Preferences
IMF	International Monetary Fund
IPR	Intellectual property right
ISO	International Standards Organization
LDC	Least-developed countries
MERCOSUR	Southern Common Market
MFA	Multifibre Arrangement (on international trade in textiles)
MFN	Most-favoured-nation
NAFTA	North American Free Trade Agreement
R&D	Research and development
TBT	Agreement on Technical Barriers to Trade
TPRM	Trade Policy Review Mechanism
TRIMs	Trade-Related Investment Measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
UPOV	International Union for the Protection of New Plant Varieties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



## **Part I**

# **Globalization and access to drugs: Implications of the WTO/TRIPS Agreement**

**Germán Velásquez  
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# Executive summary

The aim of this document is to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs, and especially about the WTO agreement on intellectual property (TRIPS Agreement) that may have repercussions in the pharmaceutical field. Therefore, the paper is meant to be non-technical in nature and does not deal with all aspects of patents nor of the TRIPS Agreement, but examines the Agreement only from the perspective of public health and access to drugs. The first part gives an introduction to the international trade system from the GATT to the WTO. The second part analyses the section on patents of the TRIPS Agreement in relation to access to essential drugs.

## The Uruguay Round and the TRIPS Agreement

In 1994, the Uruguay Round negotiations culminated in the signature of an agreement instituting the World Trade Organization (WTO). The Organization came into being on 1 January 1995 and had 132 Members in October 1997. In deciding to become Members of WTO, States also undertake to abide by its rules. A certain number of treaties on trade in goods and services are annexed to the WTO convention and are therefore binding on all Members. Among these "multilateral" agreements, the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) will probably have the greatest impact on the pharmaceutical sector.

The TRIPS Agreement establishes minimum standards in the field of intellectual property. All Member States have to comply with these standards by modifying, where necessary, their national regulations to accord with the rules of the Agreement. The main change with respect to pharmaceuticals, compared to the pre-existing multilateral conventions, is the obligation to grant patent protection to pharmaceutical product and process inventions.

## The question of drug patents

Previously, the GATT did not address the issue of the level of protection that should be accorded to intellectual property, and Member States had adopted various approaches towards drug patents. While some used to grant patents for pharmaceutical product and process inventions, some others allowed patent protection only for process inventions, thus not preventing local companies from developing different manufacturing processes for drugs that were not patent protected as a product. Other countries did not grant any form of protection for inventions in the pharmaceutical sector. Moreover, the term of protection conferred by a patent varied greatly between countries.

Under the TRIPS Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. As soon as the Agreement applies in a Member State, the patent holder should therefore have the legal means to defend against copies of patented drugs. If a

country fails to bring its legislation in conformity with the TRIPS Agreement as such, it can be the subject of a complaint under the WTO dispute settlement system, and if, after an adverse ruling against it, it still fails to comply, it then may incur trade sanctions authorized by the WTO.

## When must the Agreement's rules be applied?

The TRIPS Agreement allows developing countries a general transition period of five years (up to 2000) to amend their patent legislation in accordance with these new rules, whereas a term of ten years (up to 2005) is available for developing countries which have not yet provided product patent protection for pharmaceuticals, in order to make that change. Least-developed countries are given 11 years, with a possible extension, to harmonize their regulations with the new international obligations. For those countries which did not provide product patent protection for pharmaceuticals already as of January 1995, the Agreement will apply only to new drugs for which a patent application has been made after the entry into force of the WTO Agreement. These applications for pharmaceutical product patents are stored until modified national patent laws are adopted. As of the end of the transition period, the examination of the application has to begin, according to the conditions laid down by the Agreement. If the application is accepted, a patent will be granted for the remainder of the 20-year patent term counted from the date of filing the application. In case the invention obtains a marketing authorization before the entry into force of the new patent regulations, and if another Member State has already allowed such a patent protection for the same invention, the invention's owner may be given exclusive marketing rights for up to five years until the decision to grant or reject the patent application is made.

## Public health needs and drug patents

The Agreement requires all WTO Member States to grant patents for pharmaceutical products or process inventions for a minimum of 20 years. Although social benefits may arise from patent protection through the discovery of new drugs, the TRIPS standards derive from those of industrialized countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement.

The Agreement leaves Member States a certain amount of freedom in modifying their regulations. The terms *invention* and *discovery* are not defined in the Agreement, yet how they are defined could have important implications in the biotechnological field. The Agreement says that Member States may provide limited exceptions to the patent holder's exclusive rights in their laws. National public authorities may be allowed, within the conditions laid down in the Agreement, to issue compulsory licences against the patent owner's will when justified by the public interest. The Agreement does not prohibit parallel imports. These restore price competition for patented products by allowing the importation (without the holder's consent) of identical patented products which have been manufactured for a lower price in another country.

Member States must be aware of these possibilities when they amend their legislation. Each country's strategy in regard to globalization of drug production and distribution will have to be incorporated into its national pharmaceutical policy, a component of national health policy. It is essential that all involved in

this sector should understand what is at stake and play an active part in the reforms of intellectual property regulations now under way.

Therefore, health providers and managers should keep in mind that:

- The TRIPS Agreement establishes minimum standards in the field of intellectual property
- All WTO Members have to comply with these standards by modifying their national regulations
- Public health concerns should be highly considered when implementing the TRIPS Agreement.



# Introduction

The trade agreements emerging from the Uruguay Round\* and globalization\* are going to have a significant impact on the global market for goods and services. The production and marketing of drugs and health services could be affected to varying degrees.

The Uruguay Round served as a framework for the negotiation of a global agreement on intellectual property rights\* (Agreement on Trade-Related Aspects of Intellectual Property Rights - TRIPS\*). This Agreement is the part of the Final Act of the Uruguay Round that could have the greatest repercussions on the production of and access to drugs, especially in developing countries.

In this context, the Forty-Ninth World Health Assembly in May 1996, adopted a resolution requesting the Director-General to *"report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs"*.

The Action Programme on Essential Drugs\* has therefore drawn up a plan of action with the following objectives:

- To identify issues in the WTO Agreements relating to access to essential drugs and pharmaceutical policies, and to inform Member States about them.
- To study the implications of globalization for innovation, and for the development, production, marketing and pricing of drugs, so as to identify the possible effects of the TRIPS Agreement and other trade agreements on access to essential drugs.
- To inform Member States about the need to take steps to protect public health in parallel with the implementation of the new trade agreements.

This document is an initial response to the request by the World Health Assembly.

After a brief overview of the development of international trade, it gives pointers on how to read the TRIPS Agreement from the perspective of access to drugs. It also seeks to identify how much freedom is left for Member States to regulate the protection of intellectual property, and how they can enact legislation that both conforms with the Agreement and is consistent with health policy.

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\* The words marked with an asterisk are explained in the chapter "Definitions and terminology".



# 1. Brief historical background to the international trading system

## 1.1 The simultaneous creation of the GATT, the IMF and the World Bank

The GATT\* (General Agreement on Tariffs and Trade) came into being after the Second World War, at a time when new international organizations were being established to build an integrated world economic system. Three major issues had to be addressed for the global economy to emerge from the war and its previous disarray successfully: exchange rates, reconstruction and the organization of international trade in goods. In 1944, responding to each of these questions, the allied nations envisaged the establishment of three new international organizations.

The IMF (International Monetary Fund) and the World Bank were established by the Bretton Woods Agreements of July 1944, which were signed by 44 allied nations. The IMF was set up to manage the international monetary system. The management of exchange rates would henceforth be based on a new general principle: the fixed parity of currencies and cooperation between nations. It was implicit that States would no longer be able to freely manipulate the international exchange rate of their currency and all Member States were specifically prohibited from making competitive devaluations unjustified by their economic situation.

The World Bank, or as it was named at the time, the International Bank for Reconstruction and Development (IBRD), was initially intended to help the war-devastated European economies to finance production projects. Very soon, however, European reconstruction moved out of its sphere of competence and development financing became its main function.

In parallel with the Bretton Woods Conference, the idea of returning to an international trading system based on free trade appeared. This desire was manifested, on the one hand, in the United Nations, by a project for an International Trade Organization, and on the other hand, by the proposal for an international conference for the multilateral reduction of barriers to international trade. The two things led respectively to the "Charter Instituting an International Trade Organization", adopted in March 1948 at the Havana Conference, and a General Agreement on Tariffs and Trade (GATT), which resulted from negotiations between 23 nations that took place from April to December 1947 in Geneva.

In practice, the International Trade Organization did not come into being in 1948 as the country that initiated the process did not ratify it. However, the agreement concluded in Geneva - resulting from the first "Round" of multilateral trade negotiations - gradually became institutionalized so that it became more than just a treaty; the GATT (also referred to as the General Agreement) went on to

become, *de facto*, the main institutional framework for matters of international trade.

## 1.2 The objectives, nature and functioning of the GATT

### Objectives

The objectives of the GATT are clearly stated: they are to conclude "*reciprocal and mutually advantageous arrangements*" with a view to reducing customs duties and other barriers to trade and eliminating all discrimination in international trade.

### Nature

Since the GATT was not strictly speaking an international organization, it did not have Members but "*contracting parties*", that is, nations that adhered to the General Agreement. To become a contracting party, a State had to submit its candidature and negotiate concessions relating to customs duties and access to markets with the signatories of the General Agreement. If successful, these negotiations were concluded with a vote by the contracting parties granting this status. The GATT was thus a group of States that had different obligations and rights depending on the degree to which they had adhered to the General Agreement.

### Obligations of the contracting parties

Under the terms of the treaty, each country had to concede most-favoured-nation\* treatment to all other parties. Each signatory State also granted tariff concessions to the other parties, that is, they limited the customs duties imposed on the importation of foreign goods.

Signatory States were obliged not to take certain measures that would result in obstacles to international trade. In practice, this type of obligation amounted to a code of good conduct in trade, which Member States undertook to adhere to when they joined the General Agreement. This was principally designed to prevent discrimination between national products and imported products, to regulate the use of anti-dumping measures, to prohibit quantitative restrictions to trade, and to regulate subsidies.

Depending on the specific situation and particular characteristics of each State, some exceptions to these obligations were agreed. Certain sectors, namely services, agriculture and textiles, were largely excluded from the scope of the General Agreement. Some States also enjoyed the benefit of special rules. Since the signature of the General Agreement in 1947, developing countries had frequently pointed out that the general principles of the GATT worked against them. But their grievances were not acknowledged until the first United Nations Conference on Trade and Development (UNCTAD) in 1964, when the principle of differential treatment was invoked. UNCTAD has since become a subsidiary body of the United Nations General Assembly, well known for defending the economic interests of developing countries.

## The "Rounds"

As the essential objective of the GATT was to promote continuing liberalization of international trade, it was necessary to institute a procedure to enable the contracting parties to negotiate in this area. Therefore, rounds of multilateral trade negotiations (MTN) were instigated, during which the tariff concessions accorded by one party to another were generalized to all parties by means of the most-favoured-nation clause.

Overall, the earlier rounds of negotiations from 1947 to 1961 led to very substantial reductions in customs duties between the countries concerned.

The Kennedy Round, which lasted from 1964 to 1967, led to a further decrease in customs duties on a basis of a formula, and to the negotiation of an agreement on anti-dumping practices. But the contracting parties were not able to agree on the idea of a linear reduction in customs duties or on the problem of non-tariff\* barriers which also constituted barriers to trade.

It was at the Tokyo Round (1973-1979) that most of the agreements on non-tariff barriers were eventually signed: technical barriers to trade, government procurement, subsidies, customs valuation, import licences and anti-dumping practices.

### 1.3 The Uruguay Round and the creation of the WTO

#### The new global economic environment

At the beginning of the 1980s, it became apparent that the General Agreement was no longer so well adapted to the realities of trade as it had been in the 1950s. The complexity and volume of world trade were now very different from what they had been 40 years earlier. As the globalization of the economy progressed, international investments saw an unprecedented growth, and trade in services - not covered by the GATT rules - began to be a major interest for more and more countries, and was closely bound up with the increase in global trade in goods.

The GATT rules were also deemed inadequate in other ways: in the agriculture sector, for example, where the loopholes in the multilateral system were widely exploited and where attempts at liberalization were essentially in vain - and in the field of textiles and clothing, where an exception to the normal GATT areas of influence had been negotiated in the form of the Multifibre Arrangement (MFA). The institutional structure of the GATT and its system for the settlement of disputes were also becoming sources of concern. All these factors were enough to convince GATT Members that a renewed effort should be made to strengthen and enlarge the multilateral system.

#### Long and difficult negotiations

The seeds of the Uruguay Round were sown in November 1982 at a ministerial meeting of those GATT Members involved, held in Geneva. But it took four years of effort during which an attempt was made to explore and elucidate the issues at stake and gradually work towards a consensus, before the ministers, meeting again in September 1986 at Punta del Este (Uruguay), decided to launch

the Uruguay Round. They adopted a programme of negotiations encompassing practically all the outstanding problems of trade policy, including the extension of the trading system into several new fields, in particular services and intellectual property rights. These were the most wide-ranging trade negotiations ever undertaken, and the Ministers gave themselves four years in which to complete them.

At the ministerial meeting in Brussels in December 1990, disagreement on the nature of the commitments to be made to reform trade in agricultural products led to the decision to extend the negotiations. In December 1991, a complete draft of the Final Act containing the text of the legal instruments elaborated for all the issues raised at Punta del Este, with the exception of measures relating to access to markets, was presented in Geneva. During the next two years, negotiations oscillated continually between the apparent inevitability of failure and anticipation of imminent success. Several deadlines were set and then not met. Services, access to markets, anti-dumping rules and the proposal to establish the WTO joined agricultural trade as the principal sources of conflict. The differences of opinion between the United States of America and the European Community became the critical issue on which the long desired success of the negotiations came to depend.

In the end, the Final Act embodying the results of the multilateral trade negotiations of the Uruguay Round, was signed on 15 April 1994 at Marrakech, Morocco, by Ministers representing most of the 125 governments that had taken part.

Today, the WTO has 132 Member States. Twenty-nine countries<sup>1</sup> have filed applications to join, and talks are under way with the working groups that deal with accessions.

Previous rounds of negotiations had mainly been confined to discussions of how to eliminate trade barriers at the frontiers between countries, making for an optimal expansion of international trade and better use of the world's wealth. The Uruguay Round was much more ambitious, and was more oriented towards harmonization of national trade policies, particularly in regard to the protection of intellectual property, thereby enlarging the domain of international trade and the jurisdiction of the international organizations active in this field.

### **The results of the Uruguay Round: strengthening and enlargement of the multilateral trade system**

**Strengthening:** with the creation of the WTO, a fully fledged international organization with international legal status, its own governing bodies, and rights and obligations came into being.

**Enlargement:** this resulted from the introduction of new areas covered by multilateral trade agreements such as services (GATS\*) and intellectual property, as well as a more extensive application in the area of agriculture and textiles.

The result of the Uruguay Round is a framework convention, the Agreement establishing the WTO, under which come a variety of multilateral and

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<sup>1</sup> 32 countries in August 1998.

plurilateral sectoral conventions. Signature of the WTO convention means adhering to all the multilateral conventions (multilateral agreements on trade in goods, General Agreement on Trade in Services, and Agreement on Trade-Related Aspects of Intellectual Property Rights), whereas adhesion to the plurilateral conventions is optional (aeronautics and government procurement).

A certain number of simple basic principles run through all the instruments, which together make up the multilateral trading system.

#### *Trade without discrimination*

In accordance with the well-known "most-favoured-nation" clause (MFN), Members are bound to grant other Members' products treatment that is no less favourable than the treatment they accord to the products of any other country. Thus, no country can accord special trade advantages to another or discriminate between other countries: all countries are on an equal footing and all share in the benefits deriving from a reduction in the obstacles to trade. Customs unions and free trade areas are the exceptions that are officially authorized (Article XXIV of the GATT of 1947). An Enabling Clause dating from 1979 provides a permanent legal basis for special and differential treatment in favour of developing countries in the area of trade in goods.

A second form of non-discrimination, which comes under the heading of "national treatment", provides that once products have entered a market, they should not be subjected to treatment less favourable than that accorded to like products of national origin.

#### *Predictable and growing access to markets*

The security and predictability of access to markets depends to a large extent on the use that is made of customs duties. While quotas are prohibited on the whole, customs duties are permitted in the WTO regime and are commonly used by governments to protect national production and to raise revenue. They are, however, subject to certain rules - for example, they must not discriminate between imports - and are to a large extent "bound". Having bound a given customs duty for a specific product, a country may no longer raise it unless compensation is negotiated with the principal suppliers of that product.

The key to the predictability of a trade system often lies in the transparency of national legislation, regulations and practices. Several of the WTO agreements contain provisions in this respect. These aim to ensure transparency at the national or multilateral levels by means of formal notifications that must be addressed to the WTO.

#### *Promoting fair competition*

The WTO is not a "free trade" institution, as it is sometimes thought to be, if only because it authorizes the imposition of customs duties and, in limited circumstances, of other forms of protection. It is more accurate to say that it reflects a system of rules designed to ensure free competition that is open and without distortions. The rules on non-discrimination are aimed at ensuring conditions for fair competition, as are the rules on dumping and on subsidies. The GATT rules that defined the conditions in which governments could impose countervailing measures to these two forms of "unfair" competition have been expanded and are set out specifically in the WTO agreements.

### *Encouraging development and economic reforms*

More than three-quarters of the WTO's Members are developing countries and countries in transition towards a market economy. During the eight years of the Uruguay Round - from 1986 to 1994 - more than 60 of these countries implemented programmes to liberalize trade, sometimes as part of their negotiations to join the GATT, and in some cases independently. At the same time, developing countries and the economies in transition began to play a much more active and influential role in the Uruguay Round negotiations than they did in earlier rounds of negotiations.

The provisions of the GATT of 1947 that were intended to favour developing countries remain in place in the framework of the WTO. In particular, Part IV of the GATT of 1994\* contains three articles, introduced in 1965. These encourage industrialized countries to assist developing countries "*as a matter of conscious and purposeful effort*" in their trading activities, and not to expect reciprocity for concessions accorded to developing countries that are inconsistent with their trade development and financial needs.

### **How does the WTO differ from the GATT?**

The WTO is not simply a continuation of the GATT; it has a completely different character. The main differences are as follows:

- The GATT was a series of rules, a multilateral agreement without an institutional foundation and with just an ad hoc secretariat, originating from the attempt to establish an International Trade Organization in the 1940s. The WTO is a permanent institution with its own secretariat.
- The GATT was applied on a "provisional basis" even if, after more than 40 years of existence, governments came to regard it as a permanent commitment. Commitments entered into under the aegis of the WTO exist in their own right and are permanent.
- The GATT rules applied to trade in goods. The WTO covers not just goods, but also trade in services and trade-related aspects of intellectual property rights.
- The GATT was originally a multilateral instrument but, towards the 1980s, several new agreements of a plurilateral and hence optional nature were added to it. The agreements\* on which the WTO is founded are almost all multilateral and therefore carry with them commitments to which all Members have subscribed.
- The WTO system for the settlement\* of disputes is faster and more automatic, and thus less susceptible to blockages than the former GATT system. The implementation of the decisions resulting from the WTO settlement of disputes will be better assured.

The WTO fulfils five essential tasks:

1. Administration of the new multilateral trade agreements.
2. Provision of a forum for fresh negotiations.

3. Settlement of disputes.
4. Surveillance of national trade policies.
5. Cooperation with other international bodies in drawing up of economic policies at the global level.

## 1.4 The protection of intellectual property rights before the WTO

Intellectual property law, and especially patent law, is primarily national law. An inventor who files a patent application in a State is asking that State to recognize his exclusive right to his invention within the territorial boundaries of that State. There is not yet a world patent issued by a World Patent Office. The World Intellectual Property Organization (WIPO\*), among its other tasks, administers the application of the conventions within its field of competence. But each State alone is responsible for the patents it decides to grant or not to grant on its territory. Thus the monopoly conferred by a patent can only be accorded in States that recognize its existence. Before the Uruguay Round, many States did not issue patents for pharmaceuticals on their territory, which meant that the inventor had no particular right over his invention in that country, hence the proliferation of copies of patented drugs in some countries.

At the international level, the regulation and protection of intellectual property rights had previously been managed mainly by WIPO. But WIPO conventions, and in particular the Paris Convention, only impose general rules, such as the rule on national treatment which requires equivalent treatment for foreigners and nationals. Another example is the rule on the right of priority, which permits the organization of protection of a right in several countries. Moreover, these conventions on intellectual property are not binding upon the States that have not ratified them. The GATT itself did not deal with the level of intellectual property protection, although it contains some provisions of relevance in Articles III, IX and XX(d). These provisions were hardly discussed until the GATT ministerial meeting in 1982 brought up the problem of counterfeit goods\* in international trade. The pharmaceutical industry in some developed countries had complained of commercial losses due to the weakness of intellectual property rights protection in most of the newly industrializing countries (NIC).

Some countries appeared to be influenced by the perception that their competitiveness, dependent on technology and creativity, was not adequately protected worldwide by existing rules on intellectual property. The inadequacies of protection and rules related to IPR's enforcement, together with the absence of an international dispute settlement system led them to argue for the inclusion of intellectual property matters into the trade negotiations. Respect for intellectual property rights would then be made a prerequisite for the granting of the benefits anticipated in the WTO Agreement. Thus intellectual property was added to the agenda of the Uruguay Round trade negotiations.



## 2. Reading the TRIPS Agreement from the perspective of access to drugs

### 2.1 General presentation of the Agreement

A comprehensive Agreement on Trade-Related Aspects of Intellectual Property Rights is annexed to the WTO convention. The objectives, set out in the introduction to the Agreement, are essentially aimed at strengthening and harmonizing certain aspects of the protection of intellectual property at the global level.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter the Agreement) covers both categories of intellectual property: literary and artistic property (copyright and neighbouring rights) and industrial property (trademarks\*, patents\*, geographical indications, industrial designs, and trade secrets).

These objectives are to be realized in two ways: firstly, the Agreement requires Member States to ensure minimum standards of protection for the various rights, leaving them the choice of how they achieve this. Secondly, WTO Members must make available procedures and remedies to permit the effective enforcement of IPRs by right holders (Part III of the Agreement, not discussed in this document). The minimum standards of protection are based on the basic provisions of the principal international conventions in force (Paris 1883 and Bern 1886, as revised) administered by WIPO, with which the TRIPS Agreement will coexist without taking their place. In all the areas it covers, the Agreement provides for the application of the principle of national treatment and of most-favoured-nation (MFN) treatment. The interests of developing countries are explicitly taken into account.

This Agreement, and particularly the section on patents, is probably the element of the Final Act of the Uruguay Round that will have the most important repercussions in the field of public health, especially for access to drugs in developing countries.

### 2.2 Fundamental principles and objectives of the Agreement: the necessary balance between intellectual property and accessibility

It is generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products. In the first place this is because consumers are not in a position to judge, for example, the quality of drugs, hence the need for a monitoring and surveillance system ensured by the State. Secondly, this is because drugs play a significant social role in that they are an integral part of the realization of a fundamental human right - the right to health. That is why they

are classified as essential goods, to emphasize that they have to be accessible for all people.

The concept of accessibility is very important. It means that policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices. If the objective is accessibility, then the best possible supply must be ensured. This objective coincides with the general objective of the GATT for the last 40 years - seeking to eliminate barriers to trade so that consumers have the greatest possible access to all the goods available in the world.

The general paragraphs in the TRIPS Agreement (preamble and general provisions) stress the need to promote adequate and effective protection of intellectual property rights, but to do so as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation. The preamble to the Agreement states that:

*"Members, desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;"* (authors' emphasis).

The protection of intellectual property rights should be adapted to this objective of not generating undue distortions. Protection of intellectual property rights under the TRIPS Agreement should not lead to any discrimination in international trade.

It also states that *"Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives..."*

This means that the protection of intellectual property rights is not an end in itself but has a functional role to play in relation to the priority objectives of public policy for which these rights were created. It should be harnessed to the service of development.

Article 7 - Objectives, but also Article 8 (2), clearly indicates the subordination of the protection of intellectual property rights to public policy objectives in other areas of the State's activity, especially social and economic welfare, which depends in part on national health and social policies. This Article also stresses that the interests of all sectors involved must be taken into account. It states:

*"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

Article 8 - Principles - in paragraph (1) allows national regulations to be adapted to the fundamental objectives of public policy set by governments in certain domains, provided these regulations are not contrary to the provisions of the Agreement. Public health and nutrition receive a special mention among these

objectives, which amounts to express recognition of measures that might be adopted to guarantee accessibility. By virtue of this Article:

*"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."*

Paragraph (2) of this fundamental Article should also be mentioned, in so far as it once again expresses the need for a well-balanced interpretation of measures to protect intellectual property rights. These should be protected in such a way that they do not give rise to abuses detrimental to the necessary balance between national objectives and sectoral interests for which the State is the guarantor. Thus, in accordance with Article 8.2:

*"Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."*

At this point, Article 1 - Nature and Scope of Obligations - is of critical importance, for it establishes that Member States are not obliged to grant greater protection than that set out in the Agreement. It also recognizes that Member States are entirely free within the framework of their own legal systems and practices as to how they implement the obligations to which they have subscribed. The Article states that:

*"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."*

These general provisions were included in the Agreement to make for a balance between the rights of patent holders and their obligations *vis-à-vis* society. Member States may therefore base certain particular provisions of their national regulations on these principles. They can also bring their regulations into line with the obligations of the Agreement in such a way that their national objectives for the protection of intellectual property also accord with those imposed in other sectors of State activity which the latter deems to be necessary, provided such regulations do not contravene the Agreement.

From a social and health policy perspective, the provisions open up the possibility of establishing national regulations, taking into account the imperative of guaranteeing the best possible access to drugs.

## 2.3 Patents for pharmaceutical products and processes available all over the world

The TRIPS Agreement requires patent protection to be available for any invention in any field of technology in all WTO Member States. This provision is essentially aimed at pharmaceutical products, for which certain developing

countries, as well as developed countries, had refused to grant patents. Because of the high prices of patented drugs and the large amount of expenditure required for research and development (R&D\*) in the pharmaceutical field, some countries had chosen to imitate products patented in industrialized countries through reverse engineering\*, in order to meet their national requirements for drugs at a lower cost and to develop their technology. Other countries with no pharmaceutical industry bought these copies of patented drugs at competitive prices.

This is similar to the practice adopted by many developed countries some years ago when their own pharmaceutical industry was not yet very highly developed.

Despite the positive contribution that the patent system may bring to public health by generating incentives for innovation, it should be pointed out that the emergence of a generic\* drug sector in a number of developing countries represents a set of successful social policies that may be harder to duplicate under TRIPS.

The table below gives a detailed explanation of Article 27.

Article 27.1 Patentable subject matter	Comments
<i>... patents shall be available for any inventions, whether products or processes,</i>	Some countries only made available process patents for pharmaceutical inventions. Under TRIPS, product patents must also be available; the protection of rights on a product is much broader in scope.
<i>in all fields of technology,</i>	Some countries, unable to invest in R&D, have been excluding pharmaceuticals from patentability so as to allow the possibility for copies of patented drugs to be produced locally or imported - from other countries which also do not respect pharmaceutical patents - without the authorization of the company that invented the drug.
<i>provided that they are new, involve an inventive step and are capable of industrial application.</i>	Usual definition of the conditions of patentability of an invention.
<i>...patents shall be available and patent rights enjoyable without discrimination as to the place of invention</i>	No discrimination between national and foreign inventions, or between foreign inventions.
<i>the field of technology</i>	No discrimination between types of products - pharmaceutical or other.
<i>and whether products are imported or locally produced.</i>	Some countries have been issuing compulsory licences for lack of exploitation of patents. This type of obligation was intended to require foreign companies to set up on the national territory in order to exploit their patents, with resultant transfers of technology. The Agreement would here appear to allow these companies to import their patented product without having to transfer the related technology.

Henceforth, from the end of the transition periods, patent holders must be given the right and legal means to prevent imitation of a patented drug. If national regulations on patents do not provide it, or if it is not respected, the Member

State in question may, pursuant to the disputes settlement process, be the subject of a complaint before the WTO Dispute Settlement Body\*.

## 2.4 Non-patentable inventions: biotechnology inventions

As the general rule of the TRIPS Agreement is the patentability of any invention in any field of technology, the only exceptions authorized are those laid down by the Agreement. The Agreement authorizes certain exclusions from patentability\*, based on "*ordre public*" or morality, especially in regard to protection of human, animal or plant life, or to prevent serious damage to the environment. Members may also exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

But the main concern is biotechnological\* inventions. Article 27.3(b) provides that only plants, animals and essentially biological processes for the production of plants or animals may be excluded from patentability. However, the same provision states that micro-organisms, as well as micro-biological and non-biological processes are not covered and have to be patentable. But a doubt remains as to the nature of some of these biotechnological inventions, which find their origin in organisms existing in nature. Indeed, a patent can only be granted for an invention which is new, inventive and capable of industrial application, and not for a discovery. Micro-organisms only seem to be patentable on the condition that a real intellectual human contribution, which has to be new, is demonstrated.

Article 27.2 & 3 Exceptions	Comments
<p>2. Members may exclude from patentability inventions  <i>the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,</i>  <i>provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.</i></p>	<p>Two conditions for refusal to grant a patent:      commercial exploitation (production, distribution, sale) of the product in question is prohibited throughout the territory in the interest of "<i>ordre public</i>", morality, or the environment...by any entity whatsoever      the only possible justifications for excluding an invention for patentability under this provision are "<i>ordre public</i>" or morality, including the health and life of humans, animals or plants and the environment. Hence a legal prohibition based on other grounds is not covered by this provision.</p>
<p>3. Members may also exclude from patentability:</p> <p>a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;</p> <p>b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective <i>sui generis</i> system or by any combination thereof.</p>	<p>Specific exceptions allowed are essentially biological processes, plants and animals. But, patents for inventions of micro-organisms and for non-biological and micro-biological processes must be available. This means that inventions based on genetic engineering and gene transfers should be patentable whereas substances existing in nature should not.</p>

Given the development perspectives of biotechnology, this question is extremely important. Indeed it is the only one for which a review (in 1999) has been specifically planned by the Agreement. Developing countries rich in natural resources, should, in their new regulations, define the ambiguous terms *biotechnology* and *invention*, in order to benefit from these new provisions.

## 2.5 Effects of protection: a monopoly of working for 20 years

Traditionally, a patent confers a monopoly for working the invention upon the patent holder. Any person imitating the invention or new manufacturing process, without the consent of the patent holder, is committing an act of infringement.

### Article 28: Rights conferred

1. *A patent shall confer on its owner the following exclusive rights:*
  - a) *where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from acts of making, using, offering for sale, selling, or importing for these purposes that product;*
  - b) *where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.*
2. *Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.*

### Attenuation of the monopoly through exhaustion of rights

The exclusive right, conferred by Article 28, to import the patented product or process merits special attention on account of a footnote attached to it. This footnote states that the exclusive right to import is subject to Article 6 of the Agreement. Under that Article, the issue of exhaustion of rights cannot be addressed by the Dispute Settlement Understanding, unless it is the basis for a discrimination claim. For practical purposes, this means that countries can have the exhaustion regime they have chosen. Therefore, the Agreement does not impose any obligation on Member States on this point, which remains purely a national issue. A Member State is completely free to decide whether or not to apply the principle of the exhaustion of the patent owner's rights.

#### *What is the exhaustion of intellectual property rights?*

The issue of national exhaustion is relevant not only to importation rights but also to distribution rights. In principle, if the theory of the exhaustion of rights is not applied, the importation of a patented product (or parallel\* importation) without the authorization of its patent owner is illegal. The monopoly conferred by the patent includes not only the exclusive right to manufacture and work the patented product, but also the exclusive right to import it, if the patent owner manufactures it, or has granted a licence to manufacture it, in another country.

The exception to this general rule of prohibition is to be found in the principle of the exhaustion of rights. According to this principle, an intellectual property right is exhausted when a patented product is first put on the market with the consent of the patent holder. From the perspective of trade liberalization, it is considered that from the moment the product is marketed, the patent holder can no longer control its subsequent circulation. By virtue of this principle, the patent thus confers a monopoly on the invention (that is, the know-how) and not on the products legitimately resulting from this invention. The patent holder retains the exclusive right to manufacture the patented product and to put it on the market, but, from that moment on, has no further right over the actual product. The patent holder thus loses his monopoly of importation and sale.

*How is the principle of the exhaustion of rights to be applied?*

The TRIPS Agreement leaves Member States free to decide whether or not to apply this principle on their territory. There is, however, one further point that must be made.

One of the fundamental rules of the TRIPS Agreement is non-discrimination between Member States. There are, by virtue of the TRIPS Agreement, three main options open to a Member State wishing to apply the principle of the exhaustion of rights:

- either an international exhaustion of the rights of the patent holder, in other words, the possibility granted to a third party to import into the territory of the relevant Member State the same patented product from any other WTO Member State in which it has been put on the market with the consent of the right holder. The Member State opting for this principle would have the widest range of supply of products with the obligation (through the MFN clause) to accept products from all Member States.
- or a regional exhaustion of the rights of the patent holder (cf. the European Union), or the possibility of importing onto the territory of that State the same patented product originating from any other Member State of the same regional union;
- or national exhaustion, which amounts to limiting the circulation of products covered by the IPR in one country to only those put on the market by, or with the consent of the patent owner, in the same country.

This provision of the Agreement is very important in so far as it allows the supply of the product to be increased and prices to be moderated through competition, in other words, improving accessibility through importation. Member States could improve the accessibility of products, including drugs, by establishing that the exclusive rights of the patent holder may not be claimed in cases where products marketed with that patent holder's consent in any other country are imported. No State may complain of a breach of the Agreement on this ground.

Nevertheless, although parallel importation is legal in terms of the TRIPS Agreement, questions of economic strategy arise concerning the scope of the application of the theory of the international exhaustion of intellectual property rights. In practice, while authorizing parallel importation may help to bring down prices through competition, it may also discourage patent holders from

granting licences for local working, and thus run counter to some countries' technological development. Some authors therefore advocate a conditional authorization of exhaustion of intellectual property rights (Remiche, 1996). Why not anticipate the possibility of parallel importation only if, after a certain time has elapsed, the patent holder is not working the invention locally or is not meeting local demand at reasonable prices? In that case, the authorization of parallel imports would be motivated by the country's desire to industrialize and to supply the local market with sufficient drugs at affordable prices.

According to other authors, the effect of international exhaustion of rights would be for right holders to move towards a single worldwide price for their products, which they would be likely to seek to set at the price that the market can bear in the wealthier countries.

### **Strengthening the monopoly through the patenting of processes**

Compared to pre-existing conventions, the TRIPS Agreement strengthens the rights conferred by a process patent.

- In the first place, the Agreement imposes protection of the product obtained by the patented process as though there was also a patent for the product itself.

Article 28.1(b): "*where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process*" (authors' emphasis).

This extension of the protection of the manufacturing process to the resulting product increases the protection conferred upon the holders of know-how. The issue has been raised as to whether, in practice, the inventor of a new manufacturing process for a product already known and not protected by a patent could be granted exclusive rights to that product under the Agreement. This would only happen if the patented process used to manufacture the product was totally or partially unique and irreplaceable.

The fundamental question that then arises is whether or not it would be possible, based on this reasoning, to obtain an exclusive right to exploitation for a drug not covered by a patent, (for example, a drug included in the WHO Model List of Essential Drugs), through a new process for the manufacture of that drug. The answer would appear to be negative, since only the product directly obtained by the new process enjoys the protection attaching to the new process. This implies that a manufacturer using the old manufacturing process could not be accused of infringement of the process patent. However, the extension of process protection to a product may lead to an increase in lawsuits, which may be a deterrent to small local companies.

It is clear that developing countries will need to monitor the interpretation and application of this provision very closely.

- Secondly, Article 34 reverses the burden of proof in certain circumstances regarding process patents in infringement proceedings.

Article 34 Process patents: burden of proof	Comments
<p>For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product,</p> <p>the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.</p>	<p>If (civil) proceedings for infringement of a process patent are initiated,</p>
<p>Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:</p>	<p>the judge may decide to reverse the burden of proof (which in principle falls upon the plaintiff) and require the person suspected of infringement to prove that an identical product has been obtained using a manufacturing process different from the patented process.</p>
<p>(a) if the product obtained by the patented process is new;</p> <p>(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.</p>	<p>This is not in fact a matter left to the judge's discretion since Member States must make this reversal of the burden of proof a legal presumption, which the judge will be obliged to respect.</p> <p>Country Members must then provide for the reversal of the burden of proof in one of the following cases or both:</p> <p>1st case: only if the product made with the patented process is a new product. Therefore, Members may have to define the newness of such a product.</p> <p>2nd case: whether or not the product (obtained by the patented process) is new, the defendant is required to prove that he has not used the patented process to obtain an identical product.</p>

By virtue of Article 34, Member States must therefore provide for reversal of the burden of proof in their legislation. In other words, if the owner of a process patent suspects somebody of having used his patented process to obtain an identical product, it will be the person suspected of infringement who must prove his innocence. The Agreement calls upon Member States to provide for the application of this legal mechanism either when the product (obtained by the patented process) is new, or independently of the novelty of the product, in any case when the patent owner cannot determine that the patented process has not been used. It would seem that the first case, more restrictive since it only applies to new products, is the one best suited to the situation of developing countries.

Finally, the principal innovation of the TRIPS Agreement lies in the obligation imposed on all Member States to grant patents for drug manufacturing processes and for actual drugs. Since patents are a monopoly of the exploitation of an invention, the Agreement amounts to a limitation of supply and thus directly affects accessibility to products, including drugs.

### Extension of the duration of the monopoly

Pursuant to Article 33, the duration of protection offered will not cease until expiry of a period of 20 years from the date the patent application is filed.

This provision may result in an increase in the duration of the patent owner's monopoly in many Member States where there is no therapeutic competition. In the pharmaceutical field, the logical consequence of this provision is that drugs will be sold at high prices, as is the case for all monopoly products, for a longer period of time, and manufacturers of generic products will have to wait longer

before they can produce the drug in question and sell it at a more accessible price.

It is thus in regard to the length of protection that the Agreement will have one of its most important harmonizing effects. Unlike other provisions, which leave Member States a certain amount of room for manoeuvre, the Agreement is particularly strict and specific concerning the duration of patents.

In other words, the Agreement prohibits Member States from deciding on a special period of protection of less than 20 years depending on the field of technology, as was done by certain developing countries in the case of pharmaceutical products. The Agreement, indeed, imposes a minimum duration; but there is no provision in the Agreement that obliges Member States to issue patents for an even longer duration, as is the case in the United States and in Europe, especially for pharmaceutical products, to compensate for the length of time elapsing between the filing of a patent application and the effective marketing of the product.

## 2.6 Application of the TRIPS Agreement

With regard to the dates of application of the TRIPS Agreement, a distinction is made between the least-developed countries and developing countries, and also between countries with or without a system of patent protection for pharmaceuticals at the time of the establishment of the WTO.

Article 65 Transitional arrangements	Comments
<p>1. <i>Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement</i></p> <p>2. <i>A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement, other than Articles 3, 4 and 5.</i></p> <p>3. <i>Any other Member which is in the process of transformation from a centrally planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.</i></p>	<p>In general, industrialized countries were only obliged to start applying the provisions of TRIPS in 1996.</p> <p>Developing countries have 4 extra years to implement the provisions of the Agreement on the different aspects of intellectual property rights, that is, until 1 January 2000.</p> <p>During this transitional period, developing countries must nevertheless comply with the obligations on national treatment and MFN treatment.</p> <p>The same period of 4 years is accorded to the former socialist republics under certain conditions.</p>

(continued)

Article 65 Transitional arrangements (continued)	Comments
<p>4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.</p>	<p>For developing countries that did not grant product patent protection for pharmaceuticals before the signature of the WTO Agreement and have not done so by 1 January 2000,</p>
<p>5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.</p>	<p>these countries will benefit from a further period of five years - making a total of ten years - to take the necessary steps to ensure such protection.</p>

## For industrialized countries: 1996

In accepting to become Members of the WTO, States have committed themselves to respect the rules set out in certain agreements, including the TRIPS Agreement. In order to comply with these rules, each State is supposed to amend its legislation so that it conforms with the minimum rules laid down by the Agreement.

The industrialized countries, which mostly have a high level of protection of intellectual property already, have been allowed a period of transition\* of one year to bring their intellectual property law completely into line with the rules of the TRIPS Agreement.

## For developing countries: 2000 or 2005

Developing countries have a period of transition of five years in which to meet all the obligations incumbent upon them under the Agreement, with the exception of non-discrimination between nationals and foreigners (national treatment), or between different foreign nationals (MFN treatment). By the year 2000, they should have introduced into their national regulations on intellectual property the various rules of the Agreement they accepted by acceding to the WTO.

However, the Agreement grants a further derogation to developing countries that did not issue patents before they joined the WTO, for example, for pharmaceutical products. In practice, a number of developing countries only granted patents for drug manufacturing processes, or possibly no patents at all in the pharmaceutical sector. In this case, Article 65.4 gives them an extra five-year period of grace to introduce patentability of these products in their legislation, which amounts to a total transitional period of ten years for developing countries in respect of pharmaceutical products.

However, given the substantial time that elapses between the application for a patent for a new pharmaceutical product and authorization to market that product, strict application of this provision would have the consequence that

new patented drugs would not be marketed in developing countries until at least 2015 (2005 + about ten years of development prior to marketing).

In order to limit this effect, the TRIPS Agreement also has special transitional provisions ("mail-box" and "exclusive marketing rights" mechanisms – see below) for cases in which a State does not grant pharmaceutical products patents as of January 1995 and therefore has a period of ten years in which to do so.

## For least-developed countries: 2006

### Article 66

*"1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.*

*2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."*

Under Article 66.1, least-developed countries benefit for 10 years after the general one year transition period of 1996, while a showing of hardship may qualify them for further delays. However, they are also affected by the "mailbox" and "exclusive marketing rights" transitional provisions regarding pharmaceuticals.

## 2.7 During the transitional period

### Establishment of a "mail-box" in 1995

Article 70.8 Protection of existing subject matter	Comments
<p>8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:</p> <p>(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;</p>	<p>For countries that do not grant pharmaceutical patent protection as of 1 January 1995, independently of the transitional periods accorded to them, these countries must implement as from 1 January 1995 an adequate infrastructure to receive patent applications for such inventions of pharmaceutical products.</p>

(continued)

Article 70.8	Comments
Protection of existing subject matter (continued)	
<p>(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and</p>	These applications shall be examined at the latest in 2005 for developing countries and 2006 for the least-developed countries, in terms of the criteria for patentability set out in the Agreement, which shall be applied as if they were being applied on the filing (or priority) date of the application. This is a juridical artifice to preserve the novelty of the inventions made from 1995 onwards that will not receive patent protection for a maximum of some ten years.
<p>(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).</p>	Such inventions will receive the protection due to them (if they meet the criteria of the Agreement for patentability) as from the date of the grant of the patent after the end of the transition period and for the remainder of the 20 years counted from the filing date.

In summary, as from the entry into force of the WTO, on 1 January 1995, countries must have an adequate infrastructure to receive and store patent applications for new drugs. Since it takes about ten years to test a new molecule and authorize its marketing, the invention should remain pending until 2005 at least. This is also the date at which the TRIPS Agreement becomes applicable to some developing countries in regard to pharmaceuticals. Those developing countries therefore will not have to examine before 2005 pharmaceutical patent applications filed since 1995. If the application properly fulfils the necessary conditions for patentability (novelty, inventiveness, and capable of industrial application), which are to be applied on the filing date, the patent will be issued for a period of 20 years. This is done on the understanding that the period will commence on the filing date (1995 for example) and run for the remainder of the due term\* (until 2015 in the example).

### Possibility of exclusive marketing rights

Furthermore, if a patent application for a pharmaceutical product filed in a developing country after 1<sup>st</sup> January 1995 (or within the priority period of the Paris Convention) under the "mail-box" clause, should obtain a marketing authorization in this country before the expiry of the transitional period, (which is before 2005), the Agreement provides for the applicant to be accorded upon request exclusive marketing rights, for a maximum duration of five years, until the patent is either granted or refused.

Two conditions are necessary for the implementation of this provision: a patent must have been granted for the same product in another Member country in response to a patent application filed only after 1<sup>st</sup> January 1995 (or within the priority period of the said Convention), and a marketing authorization for this product must have been obtained in this other Member country.

These conditions have been devised to ensure that the product for which an application has been filed is indeed a genuine invention. In the pharmaceutical sector, it may then be of importance to provide the possibility of exclusive

marketing rights only for new chemical entities and to ensure that the other country in which a patent has been granted has effectively examined whether the application meets the patentability requirements.

Article 70.9 Protection of existing subject matter	Comments
<p><i>Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a)</i></p> <p><i>exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter,</i></p> <p><i>provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.</i></p>	<p>For inventions covered by "mail-box" protection, pending the granting of a patent, exclusive marketing rights shall be granted during the transitional period, as from the time the invention receives marketing approval. These rights will be accorded for a maximum of five years until such time as the patent is granted or rejected</p> <p>To be accorded these exclusive marketing rights, four conditions must be met:</p> <ul style="list-style-type: none"> <li>• a patent application must have been filed in Member State A after 1 January 1995;</li> <li>• an identical application must have been filed in another Member State B after the entry into force of the WTO Agreement and a patent actually granted;</li> <li>• a marketing authorization for the patented product must have been obtained in State B;</li> <li>• a marketing authorization is also obtained in State A.</li> </ul>

## What happens to existing patents?

Under the heading of "Protection of Existing Subject Matter", the Agreement sets out the steps that must be taken or not by Member States at the end of the transitional periods in respect of subject matter that already exists on those dates such as patents current at the end of the relevant transitional period.

Article 70 Protection of existing subject matter	Comments
<ol style="list-style-type: none"> <li>1. <i>This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.</i></li> <li>2. <i>Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. ...</i></li> <li>3. <i>There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain....</i></li> </ol>	<p>The Agreement will be binding only once it applies in a country (i.e. the end of the transition periods at the latest) and therefore is not retroactive.</p> <p>DCs in 2000, and the LDCs in 2006, must give protection, in accordance with the rules of the Agreement, to the products or processes already patented on their territory, or grant a patent for inventions already made and still fulfilling the conditions for protection stipulated by the Agreement.</p> <p>Inventions falling into the public domain before 2000 and 2006 do not incur any obligation for Member States.</p> <p style="text-align: right;">(continued)</p>

Article 70 Protection of existing subject matter (continued)	Comments
6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before that date this Agreement became known.	Compulsory licences granted before the date the Agreement became known are not subject to the provisions of Article 31. <sup>2</sup>
7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.	Applications for patents pending examination on 1 January 2000 or 2006 may be reformulated to obtain better protection under the Agreement, provided the content of the application is identical in regard to the criterion of novelty.

For countries already granting patents for pharmaceutical products, as a result of these provisions, the patents granted before 1995 continue to be governed by the old regulations up until 2000 for developing countries and 2006 for least-developed countries (subject to TRIPS national treatment and MFN which became applicable on 1 January 1996). When the transition period expires, however, the obligations of the Agreement will also apply to patents still in force. In other words, a patent still valid on that date in the country in question should enjoy a minimum of 20 years' protection from the filing date, even if the patent was originally granted for a shorter period.

Thus, at the expiry of the transitional periods, that is, in 2000 or 2005 for developing countries, and 2006 for the least-developed countries, patents existing at that time should be protected by the provisions of the Agreement. In other words, a Member State is obliged, as from that date, not only to make available the substantive provisions required by the Agreement but also to ensure that procedures and remedies are available so as to permit the right holder to take action against any infringing act under the terms of the Agreement (cf. Article 28 - "making, using, offering for sale, selling or importing" the protected product or process).

## 2.8 How can the monopoly be limited?

The anxieties and the extent of the reactions generated by the TRIPS Agreement are related to the requirement, new for some Member States, to recognize that the owners of new know-how in the pharmaceutical field are entitled to a monopoly of 20 years. Several experts from developing and developed countries fear a substantial increase in drug prices in countries that did not grant patents in the past.

<sup>2</sup> It should be noted however that the wording of Article 70.6 about the "date [this] Agreement became known" is quite unusual in an international instrument and that there are no right answers until a WTO panel takes a decision.



However, the TRIPS Agreement expressly provides two means of obtaining exceptions and limiting the exclusive rights conferred by the patent on its owner. These two provisions may be used to ensure greater accessibility to essential drugs.

## Exceptions

Article 30 of the Agreement allows "*exceptions to the exclusive rights*" of the patent holder. This is the situation in which a person can use the patent object with no need to ask the authorization of the holder and without being in an illegal situation. Those exceptions are national legal exceptions and therefore need to be set out in the national patent law.

By virtue of Article 30:

*"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

It appears from the reading of Article 30 that these exceptions are subject to three following conditions:

- They must be limited. The authors of the Agreement have attempted to avoid an uncontrolled proliferation of the number of exceptions.
- They must be duly justified; and
- They must not unreasonably affect the patentee's legitimate interests. The aim is to strike a balance between the interests of third parties (which are the grounds for the existence of the exception) and the interests of the patentee.

Apart from these three types of restriction, whose interpretation is within the WTO's remit, Member States are left a considerable margin of latitude for implementing the Agreement through national legislation. The Article does not spell out the different grounds on which Member States may base their exceptions, nor the precise cases that can be the subject of such exception to the monopoly. A number of exceptions meeting the foregoing three conditions could be envisaged. Articles 7 and 8 of the Agreement, in particular, merit consideration.

## Article 7: Objectives

*"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations"* (authors' emphasis).

## Article 8: Principles

*"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological*

*development, provided that such measures are consistent with the provisions of this Agreement* (authors' emphasis).

2. *Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" (authors' emphasis).*

Both the promotion and the transfer of technology, as well as public health or nutrition could justify derogation of the patentee's exclusive rights. Scrutiny of the exceptions existing in much national legislation gives an idea of the different possibilities (Correa, 1997):

- parallel importation of the protected product;
- acts carried out on a private basis and for non-commercial purposes;
- scientific research and experiments involving the patented invention;
- preparation of drugs by unit and on medical prescription in pharmacy dispensaries;
- a person being, in good faith, already in possession of the invention covered by the patent;
- tests carried out before the expiry of the patent to establish the bio-equivalence of a generic drug.

This last exception is at present the subject of consultations under the WTO dispute settlement system between the European Union and Canada, as Canadian legislation allows generics manufacturers to carry out experiments and tests required to obtain marketing approval, and also to manufacture and stockpile copies of patented products, before the relevant patents expire.

## Compulsory licences

Basically, the patent holder is free to exploit the protected invention or to authorize another person to exploit it. However, when reasons of general interest justify it, national public authorities may allow the exploitation of a patent by a third person without the owner's consent.

While limited possibilities of use without authorization of the right holder are permitted under Article 30, compulsory\* licences under Article 31 are another mechanism in which the patented object can be used without the permission of the rightful owner. The terms of compulsory licence are often used to denote licences granted by the judicial or administrative authorities.

French law, for example, provides that "*if required in the interest of public health*" (Article L.613-16 of the Code on Intellectual Property), patents issued for drugs may be subject to the regime of compulsory licences. The law authorizes this procedure when the patented drugs "*are only made available to the public in insufficient quantity or quality or at abnormally high prices*".

The Paris Convention left States free to grant compulsory licences "*to prevent possible abuses*" connected with monopoly. Thus, in Article 5A.(2) of the Paris Convention, "*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result*

*from the exercise of the exclusive rights conferred by the patent, for example, failure to work."*

One of the objectives of the TRIPS Agreement was precisely to limit these cases of "*utilization without the authorization of the right holder*" and to impose specific conditions on Member States.

Thus, pursuant to Article 31 of the Agreement:

- authorization of such use will be considered on its individual merits;
- authorization will be granted only if the proposed user has made efforts to obtain the licence on reasonable commercial terms;
- the scope and duration of the authorization must be limited;
- authorization is non-exclusive;
- the authorization is non-assignable;
- the predominant objective of the authorization must be supply of the domestic market;
- the authorization will be suspended if the circumstances that led to it cease to exist;
- the patent holder will be given adequate remuneration, taking into account the economic value of the authorization.

These are the main minimum conditions stipulated by the Agreement and Member States must fulfil them when they grant compulsory licences. These conditions must therefore be included before the end of the transition period in the new national legislation on patents. They must be respected whenever a compulsory licence is issued by the public authorities.

Apart from these conditions, Member States are left with a broad scope for action in regard to the grounds and reasons for compulsory licences (as is the case under Exceptions of Article 30). Five kinds of use without authorization of the right holder are expressly envisaged by the Agreement:

- licences for public non-commercial use by the Government;
- licences granted to third parties authorized by the Government for public non-commercial use;
- licences granted in conditions of emergency or extreme urgency;
- licences granted to remedy a practice determined after administrative or judicial process to be anti-competitive;
- licences arising from a dependent\* patent.

However, the Agreement does not state that these are the only cases authorized. Thus Member States are not limited in regard to the grounds on which they may decide to grant a licence without the authorization of the patent holder. They are in practice only limited in regard to the procedure and conditions to be followed. The Agreement refers to five types of licences but the list is not exhaustive. Achievement of the objective of accessibility, already mentioned, requires adequate exploitation of such possibilities for use without the permission of the patent holder in order to guarantee satisfactory conditions of supply. Compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices.

### ***Compulsory licence on the grounds of public health***

According to Article 8 of the Agreement, Member States may adopt the necessary measures to protect public health and nutrition (provided these measures are consistent with the provisions of the TRIPS Agreement). There are many instances of regulations that envisage compulsory licences for reasons of public health. In practice, if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy, such as a vaccine against AIDS or malaria, the national law may provide for the granting of a compulsory licence, under the conditions of Article 31.

### ***First attempt to obtain a voluntary licence***

In all cases in which the Agreement authorizes the granting of licences without the permission of the patent holder, the potential user is required, as a precondition for the granting of a compulsory licence, to have attempted unsuccessfully to obtain a voluntary licence contract, from the patent holder, on reasonable commercial conditions and after a certain period of time. The only cases in which such an attempt is not required are cases of national emergency, other circumstances of extreme urgency, public non-commercial use and adjudicated anti-competitive practice. The logic of this procedure is that it makes for a certain balance between all the sectors involved, obviating possible abuse by patent holders while retaining a certain flexibility, which contributes to accessibility.

### ***Utilization by governments***

The concept of a licence for utilization by the government or by authorized third parties is very important for accessibility, for in both cases, countries where drugs are supplied directly by the government may then authorize such licences for these products. In case of public non-commercial use, it is not necessary to fulfil the condition that a voluntary licence must first be applied for, although the patentee must be informed.

### ***Non-exclusivity***

The Agreement states that licences granted without the authorization of the patentee may not be exclusive. This means that any interested person may apply for such a licence, which will increase the supply of products to the highest level possible under market conditions.

### ***Second patent***

Under a number of conditions, a compulsory licence may be issued where a new invention requires the use of a pre-existing patented invention for working.

### ***Licences granted on the grounds of anti-competitive practice***

It is very important to foresee actual cases of anti-competitive practice when bringing national legislation into line with the Agreement, that is, laws on the protection of competition and anti-monopoly laws. It is also extremely important to qualify these situations to ensure that the system functions as well as possible and to avoid excessively long delays, the result of which is to reduce the practical value of such mechanisms (rapid ageing of drugs). To this end, the essential elements that should figure in national regulation of anti-competitive practice must include artificial price increases and price discrimination practices. If such situations are found and proved, and this can be done quickly and objectively, it should be possible to grant a compulsory licence.

### *Abuse of rights and local working of the invention*

The TRIPS Agreement is supposed to coexist with the conventions existing in the domain of intellectual property, and thus does not annul the provisions of the Paris Convention, but rather incorporates them into the TRIPS Agreement by reference. According to the latter, the absence of local working of patented inventions is an abuse of rights by the patent holder, and if this situation persists for more than three years, a compulsory licence may be granted. The TRIPS Agreement retains the notion that possible abuses by patent holders should be prevented. Article 8.2 authorizes Member States to take "*appropriate measures ... to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.*"

It is surely possible to maintain that for developing countries with a certain level of infrastructure, local working of a patented invention does contribute, in the pharmaceutical sector, to the "*socio-economic and technological development*" of a sector of vital importance. Hence some Member States might establish in their legislation that for "*sectors of vital importance*", if the patent holder does not manufacture the product locally and is still only importing it after three years, he or she could be required to grant a compulsory licence for local manufacture with a view to improving supply of the domestic market or price conditions.

For other countries, however, importation of pharmaceuticals may seem more appropriate; "*the existence of economies of scale and well-established know-how may result in import prices that are lower than the prices that might be proposed by local industry*" (Remiche, 1996).

The question of local working is rather loosely covered in the TRIPS Agreement. Article 2 of the Agreement states that certain provisions of the Paris Convention, including the possibility of compulsory licences for absence of local working, are applicable to all Members. At the same time, Article 27.1 appears to recognize the legality of import monopolies when it states that "*patent rights [shall be] enjoyable without discrimination ... as to whether products are imported or locally produced*".

The authors of this document have tried to interpret this question, like other "sensitive" provisions, in the light of the principles and objectives of the Agreement and of existing legislation. However, it is not impossible that a Member State may submit a complaint to the WTO Dispute Settlement Body (DSB) because it considers that another State has not transposed the provisions of the Agreement correctly into its domestic legislation, as a result of erroneous interpretation. In that case, the DSB alone would be competent to decide. There are thus a number of uncertainties attaching to the TRIPS Agreement that will be clarified in the years to come.

### 3. Conclusions: issues at stake and constraints on access to drugs

#### 3.1 The drug patents debate

The TRIPS Agreement is one of the most controversial agreements of the Uruguay Round in terms of its objectives and consequences. This is clearly shown by many of the references listed in the bibliography (see page 49).

Some authors, in favour of the TRIPS Agreement, argue that the protection of pharmaceuticals by patents should lead to:

- an increase in the flow of technology transfer and direct foreign investment to the benefit of developing countries, so improving dissemination of know-how at the global level;
- an increase in the resources devoted to R&D by local pharmaceutical companies in developing countries, resulting in the development of new drugs more suited to their own needs (patents being regarded as a stimulant to innovation, encouraging inventors to divulge and to market their inventions);
- an improvement in the welfare of the population, resulting from a wider range of better quality products;
- the end of the "brain drain" from developing to industrialized countries caused by the absence of protection for their inventions in their countries of origin.

Other writers, less optimistic or even opposed to the Agreement, respond that:

- The prices of patented drugs and the amount of patent royalties will increase with the strengthening and prolongation of the patent holders' monopoly.
- There could be a real concentration of production in industrialized countries: multinational firms will be free to export finished or semi-finished products rather than transferring technology or foreign investment directly to developing countries.
- The introduction and strengthening of patents for pharmaceutical products will certainly not lead to an increase in R&D investment by enterprises in developing countries, which have to contend with a lack of technical infrastructure, and financial and human resources. Likewise, the non-patentability of pharmaceutical products existing prior to the TRIPS Agreement gave developing countries the opportunity to progress and to

acquire basic technology through reverse engineering before being able to invest in R&D.

- The replacement or adaptation of existing infrastructures set up for the development of imitations of patented products will involve considerable costs.
- The implementation of the Agreement will involve substantial administrative costs.

It is at present very difficult to assess the impact of the TRIPS Agreement in developing countries: the market structure, the situation of the local pharmaceutical industry, the balance of payments, consumer habits, the legal environment, the country's pharmaceutical policy are all factors that make each State a special case, particularly in its perception of the effects of globalization.

There are, however, a number of points that should be mentioned.

- Intellectual property rights were included in the agenda of the Uruguay Round on the **initiative of industrialized countries**, following pressure from a variety of economic groups. A number of factors prompted this initiative: firstly, certain countries still refused to sign the Paris Convention, and there was no legal mechanism to constrain States to comply with its provisions. At the same time, freedom of trade and globalization were facilitating imitation of branded\* products, resulting in significant financial losses for multinational companies. Finally, in the pharmaceutical sector in particular, the strengthening of intellectual property rights would make it possible to contain the growing competition from the generic drugs industry (through more sustained investment in R&D as a result of patents).
- The previous rounds of GATT negotiations had been confined to discussion of ways to eliminate trade barriers at national frontiers to bring about an optimal expansion in international trade and better use of the world's resources of wealth. The Uruguay Round, much more ambitiously, set out to harmonize national trade policies, in particular in regard to the protection of intellectual property, thereby enlarging the domain of international trade and the competence of the international organizations active in that domain, and reducing the sovereign national jurisdiction of States. Because the geographical distribution of know-how is concentrated in industrialized countries, this harmonization is likely to **strengthen their existing economic superiority**, in particular by prohibiting developing countries from copying a new product by reverse engineering, and thereby developing their own technology.
- The Agreement spells out **universal standards of protection** of intellectual property, which are in practice the standards applied in industrialized countries. It also lays down some general obligations for compliance with these standards. Thus, the Agreement establishes a minimum uniform regime for intellectual property rights applicable to all Members of the WTO, irrespective of the differences in their level of development (apart from the transitional periods). This fact marks a radical break with the earlier GATT strategy of differential and more favourable treatment for developing countries adopted at the Tokyo Round.

- The TRIPS Agreement establishes, in Article 2.1, that the substantive provisions of the Paris Convention (which provides rules related to patents) shall be applicable to all WTO Members. By making this reference, the Agreement forces Member States that have not signed this convention to be bound by it, which amounts to an **express obligation to apply a treaty** without having signed it.

It is thus very clear that the Uruguay Round negotiations were largely dominated by industrialized countries and that developing countries were constrained to accept commitments sometimes running counter to their economic and social development. According to the World Development Report for 1997, "Poor countries often lose out because the rules of the game are biased against them – particularly those relating to international trade. The Uruguay Round hardly changed the picture."<sup>3</sup>

It is therefore imperative to be aware of the possible consequences of the WTO agreements, especially the TRIPS Agreement in the area of pharmaceuticals, and to optimize the mechanisms as well as the freedom provided in the Agreement to ensure availability of drugs and fair competition.

### 3.2 Some recommendations

Each country's strategy in regard to globalization in the field of the production and distribution of drugs will have to be incorporated into its national pharmaceutical policy, a component of national health policy.

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and to drugs, especially in developing countries. The new rules in the area of intellectual property could increase these countries' dependence still further.

The major implications concerning access to drugs are linked with the strengthening of the monopoly of working conferred by a patent on its holder. By 2005 at the latest, all developing countries will have to grant legal protection by patents to pharmaceutical products. Such a monopoly situation could lead to an increase in drug prices. That is why developing countries that are WTO Members should make the fullest use of the periods of transition they have been granted to transcribe the provisions of the TRIPS Agreement into their domestic law. Member States have an obligation to integrate into their patent legislation the minimal standards established by the TRIPS Agreement (patents for 20 years, no differential treatment between nationals and foreigners, reversal of the burden of proof), but the Agreement leaves certain margins of freedom that can be used to limit the adverse effects on prices and access to technology.

Thus, under the exceptions to the monopoly that are authorized by the Agreement, the law should cover the possibility of authorizing parallel importation of patented drugs sold at lower prices in another country, or establish - as has been done by the Group of Andean Countries - that a drug on the WHO Model List of Essential Drugs should be the object of a compulsory

<sup>3</sup> UNDP. *Human Development Report 1997*. New York & Oxford: Oxford University Press; 1997.

licence for public health reasons, under the conditions laid down in the TRIPS Agreement.

At the same time, a certain number of "sensitive" provisions of the TRIPS Agreement, particularly the general principles concerning the protection of health, the obligation to exploit the patent locally, anti-competitive practices, and the exclusive marketing rights conferred during the periods of transition, will necessarily be subject to interpretation in their application. It would seem fundamental for developing countries to establish a joint position *vis-à-vis* these hotly debated questions, a position founded on the demand for a balance of rights, and also of the duties of patent holders *vis-à-vis* the community.

Finally, the new provisions of the TRIPS Agreement may have, to a greater or lesser extent, serious implications for the pharmaceutical sector, even if it is impossible to quantify them at present. It is essential that everyone involved in this sector should understand what is at stake and play an active part in the reforms of intellectual property regulations that are under way. National drugs policies should define strategies and guidelines today for the new regulations on patents, the new conditions for the transfer of technology, the new orientation of R&D, etc. All of these elements could have an important impact on access to drugs, one of the main objectives of national pharmaceutical policy recommended by WHO.

# Definitions and terminology<sup>4</sup>

## Biotechnology

Integration of natural sciences and engineering in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services.

## Brand name

Name given to a drug by the manufacturer. The use of this name is reserved exclusively to its owner.

## Compulsory licence

This term is used when the judicial or administrative authority is allowed by law to grant a licence, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence).

## Counterfeit goods

Counterfeiting is a form of infringing activity. Counterfeit goods are generally defined as goods involving slavish copying of trademarks.

## Counterfeit medicine

According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging. This definition includes intellectual property and non-intellectual property elements.

## Dependent patent

A patent that cannot be exploited without using another patent. When the use of compulsory licences is necessary, it is subject to certain conditions in the TRIPS Agreement:

- a) *"the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*

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<sup>4</sup> The terms defined in this chapter are marked with an asterisk the first time they appear in the document.

- b) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- c) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."

## Drug Regulatory Authority

A Drug Regulatory Authority is designated by the State to ensure compliance with regulations applicable to drugs: issuing of marketing authorizations, authorizations of dispensaries, etc.

## Essential drugs

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage form. The WHO Model List of essential drugs is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.

## Exhaustion of intellectual property rights (see parallel imports)

This is a partial extinction of the right of the patentee - holder of the patent - consisting of the termination of certain of his prerogatives, due to exhaustion of rights. According to this theory, the patentee's right is exhausted when the product covered by it is put into circulation for the first time, if this has been done with the consent of that right holder. It follows that once the product has been put on the market, the patentee may no longer exercise control over the subsequent circulation of that product.

## GATS

The General Agreement on Trade in Services constitutes one of the new domains of competence assigned to the WTO. It is compulsory for all Member States and is aimed at liberalizing trade in services. It is likely to have consequences in the field of public health in that it may provide for Member States to open their domestic market to foreign suppliers of hospital and medical services.

## GATT/WTO

The World Trade Organization is the institutional successor to the General Agreement on Tariffs and Trade (GATT). The latter was a very particular institution: the GATT was, in fact, simply a treaty signed in 1947 by 23 nations and not an organization such as the International Monetary Fund or the World Bank, which were established at the same time. The GATT was thus a multilateral instrument whose objective was to promote and regulate the liberalization of international trade through "rounds" of trade negotiations. In 45 years, there have been eight rounds of negotiation under the auspices of the GATT. The first rounds were only concerned with sectoral reductions of customs duties. In the Kennedy Round (1964-1967) and the Tokyo Round (1973-1979), the scope of the negotiations was enlarged to include global reduction of customs duties and non-tariff measures constituting a barrier to trade (dumping, subsidies and government procurement). The last round of negotiations opened in Uruguay in 1986 and ended with the signature of the Final Act in Marrakech in 1994, establishing the new WTO. This Organization has international legal

status and henceforth all matters relating to international trade will fall within its jurisdiction. The WTO agreements consist of multilateral agreements that become binding upon Member States when they join the WTO, and plurilateral agreements that are optional.

## **GATT 1947/GATT 1994**

The General Agreement on Tariffs and Trade of 1994 is one of the WTO multilateral agreements. It consists of the original text of the GATT of 1947 as revised and modified during the various rounds of negotiations, including the concessions agreed during the Uruguay Round.

## **Generic drug**

A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

## **Globalization**

Phenomenon arising at the end of the twentieth century characterized by worldwide interpenetration and interdependence of all sectors - economic, political, social, cultural and military. In other words, globalization, as the result of technical and economic evolution, is equivalent to a transformation of society resulting in the negation of territorial frontiers.

## **Good manufacturing practice for pharmaceutical products**

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization (product licence).

## **INN (international non-proprietary name) or generic name**

Common, generic names selected by designated experts to identify new pharmaceutical substances unambiguously. The selection process is based on a procedure and guiding principles adopted by the WHA. They are recommended for worldwide use, destined to be unique and public property (non-proprietary).

## **Intellectual property**

Intellectual property rights are exclusive rights, often temporary, granted by the State for the exploitation of intellectual creations. Intellectual property rights fall into two categories: those rights relating to industrial property (invention patents, industrial designs and models, trademarks, and geographical indications) and those relating to literary and artistic property (copyright). The Agreement on Trade-Related Aspects of Intellectual Property Rights covers the main categories of intellectual property law.

## **Licence**

A contract whereby the holder of an industrial property right (patent, trademark, design or model) cedes to a third party, in whole or in part, the enjoyment of the right to its working, free of charge or in return for payment of fees or royalties.

## **Marketing authorization**

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

## **Most-favoured-nation (MFN)**

Article 1 of the GATT of 1947 requires Member States to comply with a general obligation to apply most-favoured-nation treatment. According to this Article, "Any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country, shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties". In other words, it is prohibited to treat products differently on account of their origin. In order to avoid any discrimination, any advantage accorded to one country must also be accorded to all other Members of the GATT.

## **Multilateral/plurilateral agreements**

The new Agreement instituting the WTO consists of multilateral trade agreements that are binding on all WTO Member States and plurilateral trade agreements whose acceptance by Members is optional.

The Multilateral Agreements include the multilateral agreements on trade in goods, the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreements on trade in goods comprise the GATT of 1994, the Agreement on Agriculture, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Textiles and Clothing, the Agreement on Technical Barriers to Trade, the Agreement on Trade-Related Investment Measures (TRIMs), the Anti-dumping Agreement, the Agreement on Customs Valuation, the Agreement on Pre-shipment Inspection, the Agreement on Rules of Origin, the Agreement on Import Licensing Procedures, the Agreement on Subsidies and Countervailing Measures and the Agreement on Safeguards.

The plurilateral agreements are the Agreement on Trade in Civil Aircraft and the Agreement on Government Procurement.

## **Parallel imports**

Products imported into a country without the authorization of the right holder in that country, which have been put on the market in another country by that person or with his consent. According to the theory of exhaustion of intellectual property rights, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched on the market. When a State or group of States applies this principle of exhaustion of intellectual property rights within a given territory, parallel importation is

authorized to all residents in the State in question. In a State that does not recognize this principle, however, only the patent holder that has been registered has the right to import the protected product.

## Parallel patent

This term is used when an invention is covered by more than one national patent registered by the same person in different countries.

## Patent

A title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

## Patentability

This means that a product or manufacturing process fulfils the necessary conditions for protection by a patent. There are two categories of patents: product patents and process patents.

## "Pipeline" protection

This type of protection was supported by the United States of America during the Uruguay Round but ultimately was not included in the TRIPS Agreement. It is a kind of retroactive protection, to the effect that pharmaceuticals already patented in other countries but not yet patented in the "pipeline" country (because its legislation did not grant patents for pharmaceuticals), nor marketed in that country, may be claimed for protection as such as soon as the Agreement comes into force. However, the TRIPS Agreement imposes protection only on inventions still meeting the criteria for patentability (notably because they have not yet been disclosed) on the date of entry into force of the Agreement.

## Piracy

Pirated goods are goods that violate copyright and related rights. Publishers and producers of records, films and recorded tapes are often the victims of breaches of copyright. The computer software industry is particularly affected.

## Research & Development (R&D)

The activity of devoting money and energy to researching a new technology in any field, and then developing the product or process obtained. In the pharmaceutical field, the costs of R&D are particularly high. The invention and development of a new drug requires considerable investment, hence the demand from the pharmaceutical industry for patents to be issued for all new inventions, with a view to recovery of the funds invested in R&D.

## Reverse engineering

A practice for discovering the manufacturing process of a product starting from the finished product. This practice has often been used to copy original drugs in countries that do not grant patents for pharmaceutical products.

## Settlement of international trade disputes

The dispute settlement mechanism allows countries to challenge the measures taken by their trading partners and obtain a ruling on the compatibility of these measures with the provisions of the WTO agreements. The "*Understanding on Rules and Procedures Governing the Settlement of Disputes*", that is part of the Agreement establishing the WTO, instituted the Dispute Settlement Body (DSB), which is competent to deal with any dispute arising in regard to any of the multilateral or plurilateral WTO agreements.

## Tariff/non-tariff barriers to trade

The tariff measures constituting a barrier to trade are customs duties, taxes imposed on goods entering a territory other than their territory of origin. The non-tariff measures constituting a barrier to trade are all the other regulatory or legislative measures that result in the distortion of competition in international trade. These include: commercial dumping, technical barriers to trade, government procurement, subsidies or customs valuations.

## Technical barriers to trade (TBT)

The Agreement on Technical Barriers to Trade is one of the multilateral agreements on trade in goods and therefore binding on all Members. It expands and spells out the TBT Agreement concluded at the Tokyo Round. It aims to ensure that technical regulations and standards, and testing and certification procedures, do not create unnecessary barriers to trade. Nevertheless, it recognizes that a country has the right to take measures, for example, to protect the health and life of humans and animals and for the preservation of plant life or protection of the environment, at the levels it deems appropriate, and that nothing can prevent it from taking the necessary measures to ensure respect for these levels of protection. Countries are thus encouraged to have recourse to international standards where they are appropriate, and in particular to the WHO standards of quality applicable to pharmaceutical, biological and food products; but they are not required to modify their levels of protection following standardization.

## Term of protection

This is the duration of the lifetime of a patent, in other words, the time during which the title holder to the invention may enjoy a monopoly for its exploitation. The TRIPS Agreement imposes a minimum term of 20 years for all product and process patents, measured from the date on which the patent application was filed.

## Trademark (Article 15 of the TRIPS Agreement)

*Any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combination of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.*

## Transition period

In the TRIPS Agreement, certain countries are granted periods of transition, adapted to their levels of development, constituting waivers to the time limits normally stipulated for compliance with the Agreement. Whereas all WTO Members are entitled to a one-year transition period, developing countries and, subject to certain conditions, the former socialist republics are granted four extra years to bring their legislation into conformity with the Agreement. Likewise, the least-developed countries are accorded an extra ten years to start applying the provisions of the Agreement, with a possibility of extension.

## TRIMs

The Agreement on Trade-Related Investment Measures recognizes that certain measures may have the effect of restricting or distorting trade. It provides that no Contracting Party may apply trade-related investment measures (TRIMs) that are not compatible with Article III (national treatment) and Article XI (general elimination of quantitative restrictions) of the General Agreement. To this end, an indicative list of TRIMs agreed to be incompatible with these Articles is annexed to the Agreement. This list includes measures requiring an enterprise to buy a certain volume or a certain value of locally produced goods (provisions relating to the content of elements of local origin) or which limit the volume or value of the imports this enterprise may purchase or use to an amount linked with the volume or value of the local products it exports (prescriptions relating to the balance of trade). The Agreement provides for compulsory notification of all TRIMs that do not comply and their elimination within two years for developed countries, five years for developing countries and seven years for the least-developed countries.

## TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights covers a new field in multilateral international trade law. It was proposed that this subject should be included in the multilateral trade negotiations of the Uruguay Round in an attempt to remedy problems of international piracy and infringement of intellectual property rights. The Agreement establishes minimum standards of protection for each category of rights. These standards should be integrated into the national legislation of all WTO Members, and should be applied in accordance with the principles of most-favoured-nation treatment and national treatment. They subsume and extend to all WTO Members the substantive obligations of the main treaties administered by WIPO, i.e. the Bern Convention for the Protection of Copyright and the Paris Convention for the Protection of Intellectual Property, with the addition of other obligations when necessary to complement the scope of these Conventions. The TRIPS Agreement, as an entity in the block of multilateral agreements, binds the obtaining and maintenance of customs benefits in the framework of WTO to respect for intellectual property rights by the State in question. It is the agreement in the Final Act of the Uruguay Round that could have the most implications for the production of and access to drugs, particularly in developing countries.

## Unfair competition

This is defined in the TRIPS Agreement as any act of competition contrary to honest trade practices, leaving it to the authorities in each country to define the concept of commercial honesty. More generally, it is defined as wrongful actions committed in professional practice, of a nature such as to incur the civil liability of those committing them. Such actions would be likely to attract clients or turn them away from a competitor in a wrongful manner.

## Uruguay Round

"Rounds" of negotiation were instituted when GATT was established. The GATT agreement itself results from the first round of negotiations, since the objective in 1947 was to get States to negotiate in the domain of international trade with a view to granting mutual trade concessions. When the GATT became institutionalized, it was decided to keep the idea of rounds of multilateral trade negotiations (MTN). Thus there have been in succession the Geneva, Annecy and Torquay Rounds, followed by the better known Dillon Round, Kennedy Round, Tokyo Round and Uruguay Round. It was the round that lasted longest (1986-1994) and also the most ambitious, being the origin of the establishment of the WTO and a string of multilateral agreements.

## WHO Certification Scheme

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO certificate, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practice. This system is particularly useful for countries with limited capacity for quality control of drugs.

## WIPO

The World Intellectual Property Organization was set up in 1970 to manage the protection and regulation of intellectual property rights. It replaced the Union for the Protection of Intellectual Property, an association of States with permanent independent bodies established by the Paris and Bern Conventions. In 1996, WIPO had 140 Member States and was administering 18 international conventions, the most important of which are the Paris Convention on intellectual property (1883 - 114 Members), the Bern Convention on copyright (1886 - 102 Members), the Madrid Agreement on the international registration of marks (1891 - 37 Members), the Patent Cooperation Treaty (1970 - 68 Members), the Budapest Treaty on the international recognition of the deposit of micro-organisms (1977 - 26 Members) and the International Union for the Protection of New Plant Varieties (UPOV-1961- 24 Members). Since the existing conventions in the field of intellectual property do not provide for any system of sanctions for non-compliance, it was proposed in the WTO negotiations to introduce the obligation to ensure minimal protection of intellectual property rights, and to make compliance a condition for the granting of customs concessions. The TRIPS Agreement will coexist with the earlier conventions administered by WIPO, without replacing them.

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Accessible by e-mail: [hecon8f@who.ch](mailto:hecon8f@who.ch)

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**Languages:** English, French, Spanish.

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**Language:** English.

**Address:** Oldwicks Press Limited, 5 Links Avenue, Felixstowe, Suffolk, IP11 9HD, United Kingdom.

**Summary:** Analysis of the consequences of patent protection of pharmaceutical and biotechnology products in Brazil. More specifically, the following points are developed: the controversy in Brazil on the issue of the patentability of pharmaceutical products, the pharmaceutical industry in Brazil, a market study of patent protection of pharmaceutical products in Brazil, a study of the consequences in terms of costs and delays in the field of R&D.

## CANADA

- Torremans P. Compulsory licensing of pharmaceutical products in Canada. *International Review of Industrial Property and Copyright Law*, 1996, 27:3.

**Key words:** Canada, patent, pharmaceutical product, licences, generic products, NAFTA.

**Language:** English.

**Address:** IIC, VCH Verlagsgesellschaft mbH, P.O. Box 101161, D-69451 Weinheim, Germany.

**Summary:** Presents the traditional Canadian approach to patents for pharmaceutical products based on lax regulation of compulsory licences, the changes made to the legislation following signature of the TRIPS and NAFTA Agreements and the implications for the Canadian generic drugs industry.

## EGYPT

- Abouelenein AA. *Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the pharmaceutical industry in Egypt*. Federation of Egyptian Industry; Cairo, June 1996.

**Key words:** Egypt, patent, drug, price, pharmaceutical industry.

**Language:** Arabic, English.

**Address:** Federation of Egyptian Industry, Cairo, Egypt.

**Summary:** A view of a member of the Board of the Association of Egyptian Industries on the effects of the TRIPS Agreement on the country's pharmaceutical industry compared with its present state, and the economic, social and health effects likely to ensue.

- Ghorab MG. *Agreement on intellectual property and pharmaceuticals in Egypt*. Egypt, 1996.

**Key words:** Egypt, drug, patent, price, R&D, investments.

**Language:** Arabic.

**Address:** Medicinal drugs holding company (of which Mr Ghorab is the Chairman), Egypt.

**Summary:** Brief presentation of the current drug situation in Egypt followed by an outline of the solutions envisaged to take account of the TRIPS Agreement, in particular, policies on registration and pricing, support to R&D activities, and instigating strategic alliances. Analysis of the advantages accruing from patent protection for the pharmaceutical industry and the economy in Egypt.

- Shaarawi NM. *Intellectual property rights - Egypt*, Glaxo Wellcome Egypt, SAE, 1993.

**Key words:** Egypt, patent, drug prices, R&D.

**Language:** English.

**Address:** Glaxo Wellcome Egypt.

**Summary:** The view of a multinational established in Egypt on the possible consequences of the TRIPS Agreement on drug prices and the advantages resulting from it for the Egyptian pharmaceutical industry in the field of R&D.

## INDIA

- Ahuja SD. GATT and TRIPS - The impact on the Indian pharmaceutical industry. *Patent World*, September 1994, pp 28-34.

**Key words:** India, patent, pharmaceutical product.

**Language:** English.

**Address:** Armstrong International Limited, The Courtyard, 12 Hill Street, St Helier, Jersey, JE2 4UB, United Kingdom.

**Summary:** Describes the issues surrounding the reform of the 1970 Patent Act in order to ensure its conformity with the TRIPS Agreement, existing distortions, the modifications that need to be made and the consequences for the Indian pharmaceutical industry.

- Debroy B. *Beyond the Uruguay Round: the Indian perspective on GATT*. Response Books, 1996.

**Key words:** India, patent, pharmaceutical product, essential drugs, micro-organisms, R&D, prices.

**Language:** English.

**Address:** Response Books, a division of Sage Publications India Pvt Ltd, M-32 Greater Kailash Market I, New Delhi 110048, India.

**Summary:** Developments on the exceptions of Article 27 determining non-patentable products, followed by analysis of the consequences of the Agreement in India in terms of drug prices and repercussions on essential drugs.

- Dubey M. *An unequal treaty: world trading after GATT*. New Delhi, 1996.

**Key words:** India, WTO, GATS, TRIMs, agriculture, textiles, settlement of disputes, patent, drug, licence, investments, transfer of technology.

**Language:** English.

**Address:** New Age International Limited Publishers, 4835/24 Ansari Road, Dayaganj, New Delhi 110 002, India.

**Summary:** Analyses the impact of the different agreements and the WTO system on developing countries and India in particular. History of the difficult negotiations leading up to the signature of the TRIPS Agreement and discussion of the pros and cons of the Agreement for developing countries, the special case of the protection of plant varieties and, finally, the various possibilities for making the obligations under the Agreement more flexible.

- Karandikar SM. *Indian drug industry after GATT*. Bombay: World Trade Centre, September 1994.

**Key words:** India, pharmaceutical industry, patent.

**Language:** English.

**Address:** MVIRDC, World Trade Centre, Centre 1, 31st floor, Cuffe Parade, Bombay 400 005, India.

**Summary:** Comprehensive study of the pharmaceutical industry and the Indian health system. Analysis of the consequences of the signature of the TRIPS Agreement for the Indian pharmaceutical industry and access to drugs.

- Otten A. The GATT/TRIPS Agreement and health care in India. *The National Medical Journal of India*, 1995, 8:1.

**Key words:** India, patent, pharmaceutical product, costs, R&D.

**Language:** English.

**Address:** National Medical Journal of India, All Indian Institute of Medical Sciences, Ansari Nagar, New Delhi 110029, India.

**Summary:** An attempt to respond to questions that are controversial in India, such as why the TRIPS Agreement should necessarily have dramatic effects on drug prices, and how pharmaceutical patents would lead to more R&D, to improve access to drugs.

- Krishna Iyer VR, Chinnappa Reddy O, Desai DA, et al. Report Peoples' Commission on GATT. *On the constitutional implications of the final act embodying the results of the Uruguay Round of multilateral trade negotiations*. Centre for Study of Global Trade System and Development, 1996.

**Key words:** India, WTO, GATS, TRIMs, agriculture, textiles, patent, drug, prices, licence, investments, transfer of technology, essential drugs.

**Language:** English.

**Address:** Centre for Study of Global Trade System and Development, A 388, Sarita Vihar, New Delhi 110 044, India.

**Summary:** A chronology of the national and international events that led up to the signature of the Final Act, with an historical account of the creation of the GATT and the earlier rounds of negotiations. The Indian Government's handling of the Uruguay Round negotiations is the subject of another chapter. The bulk of the report is devoted to the critical provisions of the Final Act agreements, their political and economic impact and their constitutionality.

- Pillai AM. Impact of GATT Agreement on drug prices. *J. Indian Med. Assoc.*, March 1995, 93:3.

**Key words:** India, prices, drug.

**Language:** English.

**Address:** Journal of the Indian Medical Association, AMM House, 53 Creek Row, Calcutta 700014, India.

**Summary:** Discusses the implementation of the TRIPS Agreement, and the increase in prices that could follow as a challenge to the pharmaceutical industry, the government and the medical profession.

- Redwood H. *New Horizons in India - the consequences of pharmaceutical patent protection*. Oldwicks Press Ltd., 1994.

**Key words:** India, pharmaceutical industry, patent, prices, R&D.

**Language:** English.

**Address:** Oldwicks Press Limited, 5 Links Avenue, Felixstowe, Suffolk, IP11 9HD, United Kingdom.

**Summary:** The rise of the Indian pharmaceutical industry as a result of the Patent Act of 1970. Analysis of the myths and expectations relating to the implementation of the TRIPS Agreement in India: the introduction of patents to the Indian drugs market, the effects on prices, expectations for R&D of new products. The last part looks at possible options for the future.

- Sen B. *The Uruguay Round: implications for world trade*. New Delhi: 1996.

**Key words:** India, pharmaceutical industry, patent, prices, R&D.

**Language:** English.

**Address:** Jawahar Publishers and Distributors, New Delhi, India.

**Summary:** Evaluation of the stake of the new WTO agreements for developing countries. Focuses on the situation of pharmaceutical and biotechnological products in India.

- Rajiv Gandhi Institute for Contemporary Studies. *Indian S&T after GATT: an agenda for action*. RGICS Project No. 9.

**Key words:** India, patent, micro-organisms, plant varieties, R&D.

**Language:** English.

**Address:** Rajiv Gandhi Foundation, Jawahar Bhawan, Dr Rajendra Prasad Road, New Delhi 110 001, India.

**Summary:** Analysis of the TRIPS Agreement's influence in the field of science and technology, and some suggestions on how India can benefit from the post-GATT era.

#### **ITALY**

- Challu PM. Effects of the monopolistic patenting of medicine in Italy since 1978. Special issue on the management of international intellectual property. *Int. J. Technology Management*, 1995, 10(2/3):237-251.

**Key words:** Italy, patent, drug prices, R&D.

**Language:** English.

**Address:** International Journal of Technology Management, 17 Beeward Close, The Leyes, Wolverton Mill, MK12 GLJ, United Kingdom.

**Summary:** The study concentrates on four fields: the impact of patents on prices, the attitude of national laboratories and the consequences for national production, the effects of the monopoly conferred by patents on the capacity for innovation, and the influence of patents on trade in pharmaceuticals in Italy.

- Scherer FM, Weiburst S. Economics effects of strengthening pharmaceutical patent protection in Italy. *International Review of Industrial Property and Copyright Law*, 1995, 26:6.

**Key words:** Italy, patent, pharmaceutical product, costs, R&D.

**Language:** English.

**Address:** IIC, VCH Verlagsgesellschaft mbH, P.O. Box 101161, D-69451 Weinheim, Germany.

**Summary:** Economic study of the consequences of the introduction of pharmaceutical patents in Italy from the standpoint of R&D expenditure, the introduction of new drugs, and direct investment by multinational companies.

#### **JORDAN**

- Badwan AA. *Implications of joining WTO on the Arab pharmaceutical industry*. Jordan, 1996.

**Key words:** Jordan, patent, mark, drug, industry, prices, competition, imitation.

**Language:** English.

**Address:** Jordanian Pharmaceutical Manufacturing Co., Jordan.

**Summary:** Overview of the main provisions of the TRIPS Agreement likely to affect developing countries and the situation of the Arab drug industry.

## **Part II**

**Presentations at the ad hoc working group on  
the Revised Drug Strategy  
held in Geneva on 13 October 1998**



# 1. Speech of the WHO Director-General, Dr Gro Harlem Brundtland

Mr Chairman,  
Executive Board Members,  
Representatives from Other Member States,  
Invited Guests,  
Colleagues,  
Ladies and Gentlemen,

This gathering is one example of a new, more open approach to the work of WHO's Executive Board. I welcome you into this process and invite you to participate actively and share your experience.

The 51st World Health Assembly in May saw a debate on the revised drug strategy resolution. We all remember the outcome. After hours of negotiations the resolution was referred back to the Executive Board. This week you are meeting as a working group of the Board to reconsider the issues.

The real purpose of this week's work is to move our thinking further - on how we can secure fair and equitable access to drugs - on the health implications of expanded world trade - and on how WHO can best play its role to reach that goal. It is not a quick fix. We need to create a process that can build momentum for change. I wish to look ahead – one year, two years - and be able to set an agenda that we can pursue together.

Before looking ahead, let us first take this opportunity to reaffirm WHO's strong commitment to national drug policies and to the concept of essential drugs and vaccines.

As some here may recall, in 1975 – faced with serious problems of availability, cost, quality, and use of drugs in developing countries – the World Health Assembly adopted a resolution which first put the concepts of "national drug policies" and "essential drugs" into the international public health vocabulary. In 1981, the Action Programme on Essential Drugs was formed to provide direct support to countries to implement these concepts.

At the beginning, the concept of a national drug policy was unfamiliar. Few countries had essential drugs lists. National treatment guidelines were rare. Teaching about prescribing was unsystematic. Of greatest concern, was the observation that less than half the world's population had regular access to essential drugs.

Today, nearly 90 countries have national drug policies in place or in preparation. Three out of four countries – over 140 in total - have adopted national essential drug lists. These national lists are widely used for drug purchases, training, and public education about medicines. Nearly 100 governments have developed national treatment guidelines. And the WHO approach to prescriber training is

being adopted by leading medical universities in countries at all levels of development.

Most importantly, through a combination of public and private health systems, the absolute number of people with access to essential drugs has nearly doubled over the last twenty years.

These few examples illustrate what can be achieved when countries, with support from WHO and other international organizations, become committed to a shared vision. But there is still much to do.

Medicines are still unavailable or unaffordable for too many people – especially the poor and those most in need. Prescribing and consumer use of medicines is too often ineffective, wasteful, or even harmful. Poor quality drugs constitute a continuing health hazard.

Our aim must be to ensure equity of access to essential drugs, rational use, and quality. This is simply part of the fundamental right to health care. Achieving these objectives remains one of WHO's highest priorities.

We remain committed to national drug policies as part of national health policies. The national drug policy process can and should engage the public sector, professional bodies, the private sector, consumers, academics, and other concerned partners. Together they can develop a common vision and plan of action.

WHO will continue to promote the essential drugs concept. Essential drugs and vaccines save lives and improve health. In updating the WHO Model List of Essential Drugs, we will look carefully at the evidence for drug selections. We must ensure that the list reflects current therapeutic needs and changing drug resistance patterns.

We will work with governments, other UN agencies, NGOs, the private sector and other interested partners to find new ways to increase access, to improve the use of medicines, and to assure the quality of medicines.

We are structuring our work to ensure that WHO speaks with one voice in the area of pharmaceuticals and essential drugs. Through the Action Programme on Essential Drugs, WHO remains committed to working with countries to develop and implement effective national policies and programmes.

Let us consider more carefully the critical issue of access.

As we have seen, much has been achieved during the last twenty years. Nevertheless, one-third of the world's population still has no guaranteed access to essential drugs – and most of these people have little or no access to primary health services either. That has to change and that should in itself be a strong unifying force in our efforts.

The inequities are striking. In developed countries, there may be one pharmacist for every 2000 to 3000 people. A course of antibiotics to cure pneumonia can be bought for the equivalent of two or three hours' wages. One-year treatment for

HIV infection costs the equivalent of four to six months' salary. And the majority of drug costs are reimbursed.

In developing countries, there may be only one pharmacist for one million people. A full course of antibiotics to cure a common pneumonia may cost one month's wages. In many countries, one year of HIV treatment - if it were purchased - would consume the equivalent of 30 years' income. And the majority of households must buy their medicines with money from their own pockets.

How can such profound inequities be addressed? What actions can be taken to address the needs of those who do not have access to essential drugs?

We must work with countries - especially those in greatest need - to put into practice what is already known about drug management, distribution systems, and financing systems.

We need to gather evidence on which approaches are most effective. The Action Programme on Essential Drugs is currently undertaking initiatives which address drug supply strategies and health reform, generic substitution, price information, effective drug regulation, and drug insurance.

We must work with all interested partners - governments, UN agencies, the private sector, NGOs and others - to find innovative approaches to bring prices down, to increase financial resources, to improve supply systems, and to ensure that drugs arrive where they are needed. I invite you in your discussions today, and throughout the week, to identify additional ways in which WHO can help tackle the problem of access to essential drugs.

Let us turn to the issue of trade and health.

The revised drug strategy resolution addressed many issues - such as national drug policies, drug regulation, quality assurance, drug prices, ethical drug promotion, and patient information. But it was the question of new trade agreements and pharmaceuticals which attracted the most attention.

What is the relationship between trade and health? Do health people and trade people have anything to say to each other? Yes we do and we have been talking for quite some time already. Here are some examples:

Food safety has been on the leading edge of WHO interactions with the World Trade Organization. As a result of early WHO efforts, the standards, guidelines and recommendations of the Codex Alimentarius are specifically stipulated as the international reference for food safety in the relevant WTO agreement.

Earlier this year, WTO transmitted to all Member States the information that there has not been a documented outbreak of cholera from commercially imported food. This appears to have contributed to the European Union lifting its embargo on fishery products from a number of developing countries.

With respect to pharmaceuticals - including biologicals such as vaccines - international norms and standards are not specified in WTO agreements. Here, WHO's role must be viewed as the only representative organization worldwide

with a mandate and technical expertise for setting health-related norms and standards.

Aside from the question of norms and standards, WHO has official observer status on the WTO committees which administer the Technical Barriers to Trade (TBT) and the Sanitary and Phytosanitary (SPS) agreements. This status allows WHO to intervene in these committees to present public health perspectives, to provide information to WHO Member States, and to assist in solving problems as they arise in the implementation of agreements.

Where public health issues are involved, WHO has been called upon to provide expert views in the WTO dispute settlement process. WHO also has enlisted WTO collaboration on WHO documents on health aspects of trade and has joined WTO in-country training sessions.

On some points of health-trade interaction, WHO actually has the leading role. Take the International Health Regulations - a legally binding instrument administered by WHO. It covers the health aspects of the movement of people and goods. WHO has invited input for revision of these regulations from the concerned WTO committee.

What can we learn from WHO's experience thus far in trade and health? There are several lessons, I believe.

First, there clearly are important trade issues which require a public health perspective. WTO does not have that expertise. WHO and WTO need to work together within the international system. Food safety, international health regulations, trade in health services, pharmaceuticals, and biologicals are all areas in which health and trade intersect.

Second, as a source of technical expertise and holder of public health values, WHO must ensure that health concerns are weighed appropriately when trade and health intersect. When trade agreements affect health, WHO must be involved from the beginning. We need to analyse and monitor how new international agreements can support public health.

Third, we must recognize that the intersection of health and trade brings together a stunningly diverse set of organizations, perspectives, and values. You may see this diversity as a barrier. I see it as an inescapable reality and perhaps even an opportunity. If, through this broad process that I am calling for today - health and trade people come to understand each other better - then we will have achieved a great deal.

WHO can assist, but governments must also develop their own views. After all - it is the same governments that are sending their representatives to the different negotiations. Governments must be consistent and send the same message in different international bodies.

We cannot slice the world into pieces - one for health, one for trade and one for environment. Health Ministers and Trade Ministers must meet and speak. My message to countries is that they install mechanisms to secure better coordination between ministries responsible for trade and health - as well as other relevant ministries - seeing to it that public health concerns are duly taken into account.

Fourth - and most important - I am convinced that the way forward is through open dialogue and direct interchange among interested partners. Yesterday I met with Mr. Ruggiero, Director General of the World Trade Organization. I urged that WTO take a more active role in understanding the health perspective and I confirmed that WHO will work seriously to analyse the trade perspective. We agreed to meet twice a year to address a prepared agenda related to world trade and health.

Appropriate mechanisms are needed to assist trade officials to understand the health implications of WTO agreements. Similarly, mechanisms must be found to ensure that health officials understand clearly the relevant sections of trade agreements. Here WHO has an important role to play.

Let's then move to the development of needed new drugs.

Never has the world had so many therapeutic weapons for the diseases which afflict humanity. At the same time, there is a critical need for certain new drugs and vaccines. This is true for emerging diseases, but also true because of the serious threat from growing resistance to drugs for common killers such as malaria, tuberculosis, bacterial meningitis, and pneumonia.

To develop new drugs we need an innovative pharmaceutical industry, with appropriate incentives for innovation and protection of intellectual property rights. Experience demonstrates that protection of intellectual property rights goes hand-in-hand with successful research and development.

The WTO agreement on intellectual property, or "TRIPS" as the agreement is commonly called, provides WTO members with the minimum global standard for intellectual property. WTO member countries are working to see how best to implement this agreement.

Let us agree: countries are affected in different ways by the new trade agreements - according in part to their level of development.

From a public health perspective, there are a few key questions: will drug prices increase? Will production and availability be affected? Will R & D increase on drugs for priority public health problems? On these questions, let me say, WHO will be watching. I invite governments, industry, NGOs and other partners to establish with WHO an appropriate mechanism for monitoring the actual effects of the new trade agreements. Let us work together on these questions.

During the many hours spent on this resolution in May, the group was unable to agree on common language concerning trade agreements and pharmaceuticals. A lot of effort was put into some key words.

Today let us ask ourselves: What do we want to achieve? What is the best action taken by Member States - in the Executive Board, in the World Health Assembly and by the WHO Secretariat? The Secretariat can support and assist - and is ready to engage with all its energy in this critical endeavour. It is you, the Member States who must decide the guidelines. I urge you to opt for a broad process with perspectives for change towards equitable access to essential drugs.

Finally, let us talk about partnership.

I have committed WHO to reaching out - to the private sector, to NGOs, and to others in civil society who have an interest in health development and who can make a contribution. We must accept the legitimacy of all stakeholders. Each has a commitment to health - each in its own way.

Last Friday we had our first roundtable meeting with NGOs active in pharmaceuticals and essential drugs. Our discussions covered a number of areas, including the role of consumer organizations and health-related NGOs, access to drugs in developing countries, and rational use of drugs. I was impressed by the knowledge, diversity, strength of commitment, and openness of these organizations.

Next week I will hold a similar roundtable with senior executives from the research-based pharmaceutical industry. There we hope to map out the challenges, to see better what WHO and industry can achieve together. The concept of "roundtables" applies to a process, not simply a meeting. There will be follow-up work from these two roundtable discussions. We will ensure that the roundtable process includes all key partners. We are challenging our partners to do more to promote rational use of drugs, access to essential drugs and innovation for needed new drugs. There have been and will be similar meetings with partners concerned with breast-milk substitutes, tobacco cessation, diagnostics, and other areas.

Reaching out is a broad concept. I will ask the Regional Offices to gather information on the local factors inhibiting access to drugs in their regions - and the results from these surveys will be shared with other agencies such as the World Bank, UNDP, UNICEF and UNCTAD so that together we may design programmes that can improve access to essential drugs.

I also wish to see WHO work with the World Bank, UNIDO and UNDP to stimulate the transfer of technology and capacity building in local production at a country level, as appropriate.

Finally, I welcome the good relations between WHO and the Movement of Non-Aligned Nations - grouping the majority of the developing world. I have noted the commitment to a wide range of pressing health needs, including access to essential drugs, expressed in recent meetings of the Ministers of Health and Heads of State.

Mr Chairman, Colleagues, Ladies and Gentleman,

This will be a demanding few days. This represents a new way of working for the Executive Board - maybe you find it effective. Maybe you will suggest new ways. You may see it as a challenge, but it is also an opportunity.

I wish you well in your deliberations.

Thank you.

## 2. World Intellectual Property Organization (WIPO)

### Speaker: Richard Wilder

#### *WIPO's Role and Activities in the Field of the Protection of Patents*

##### **Role and Activities of WIPO**

The World Intellectual Property Organization (WIPO) is an intergovernmental organization with headquarters in Geneva, Switzerland. It is one of the 16 specialized agencies of the United Nations system of organizations. There are, as of September 21, 1998, 171 States which are members of the Convention establishing WIPO. WIPO is responsible for the promotion of the protection of intellectual property throughout the world through cooperation among States, and for the administration of various multilateral treaties dealing with the legal and administrative aspects of intellectual property. Its principal activities are the progressive development of norms in the field of intellectual property, administering certain treaties for global protection for intellectual property, in particular for patents, trademarks, industrial designs and development cooperation.

One of the main tasks of WIPO consists in cooperating with developing countries in their efforts for development as far as intellectual property is concerned. In the field of industrial property, the main objectives of WIPO's cooperation with developing countries are:

- (i) to encourage and increase, in quantity and importance, the creation of patentable inventions by their own nationals and in their own enterprises, and thereby to enhance their technological self-reliance and their competitiveness in international markets;
- (ii) to improve the conditions of acquisition of foreign patented technology, that is, making those conditions more favourable to them than they are today;
- (iii) to increase their competitiveness in international trade through a better protection of the trademarks and service marks of relevance in such trade and through a more effective use of trademarks and service marks in commerce;
- (iv) to facilitate their access to the technological information contained in patent documents and its dissemination to potential users of such information.

In order to achieve those objectives, most developing countries are in need of enacting or modernizing domestic legislation, strengthening governmental

institutions, acceding to international treaties, having more specialists in government, in industry and in the legal professions, and having better access to, and making better use of, industrial property information, particularly patent documents. WIPO provides training and technical assistance to developing countries in all of these areas and has been doing so for many years. Recently, at the request of the WIPO member states, these training and technical assistance activities have been expanded to include matters relating to the implementation of the TRIPS Agreement administered by the WTO.

### **Patent Protection and Procedures for Application and Legal Effect of Grant**

Turning now specifically to patent protection, there are several key points to be borne in mind to best gauge the economic impact of the patent system. These points apply equally to patent protection for pharmaceutical processes and products. First, the patent system encourages people to invent. By granting exclusive rights in an invention, for a limited period of time, people, in particular those engaged in commercial enterprises, are more willing to invest in the resources necessary to make and commercialize the invention. The patent system also encourages people to disclose inventions, rather than retain them as trade secrets.

Applications for patent protection must be filed in every country (or regional offices, where they exist) where protection is desired. The decision of whether to file or not is a business decision based upon the cost of obtaining protection versus the value of that protection in a given country. It is rare that a person or company will file for patent protection in every country having a patent system. Further, many patent systems require the payment of fees to keep both applications and granted patents in force.

A patent, to be valid, must meet certain conditions. First, it must relate to subject matter that is not excluded from patent protection. A diminishing number of countries still exclude pharmaceutical products from patent protection. WIPO advice is not to exclude such subject matter. Further, the invention for which protection is sought must be novel and involve an inventive step. That is, it must not be an invention that is obvious to persons that are skilled in the area of technology with which the invention is concerned. Further, the invention must be useful or be applicable in some area of industry. In addition, the patent application must disclose the invention such that persons skilled in the relevant area of technology can also make and use the invention.

Many offices require that an application, once filed, be subject to a search and examination to determine if it meets the requirements for patentability. A search involves looking for "prior art" - that is, other prior patent documents or other literature that may be relevant to the invention. Following the search, the invention is examined to compare it to the "prior art" to determine if it meets the requirements of patentability. If the conditions for patentability are met, the patent is granted and will have effect for a limited period of time – at least 20 years from the filing date. There is no requirement that every patent office have all the resources necessary to do such a search and examination themselves. For example, many offices rely on the work that has already been done in respect of the same invention by other offices. Moreover, some offices grant protection without a search and examination having been performed. It should be noted that WIPO administers a program of assistance whereby searches and

examinations can be performed for patent offices that do not have the facilities to do so themselves.

The patentee has the right to prevent others from using the invention without his permission. Thus, it is a “negative” right. The grant of a patent does not give the patentee a “positive” right to perform the patented invention. Thus, other laws, such as those for the protection of the environment or human or animal health may constrain the use to which the patentee may put the invention. Such constraints include, for example, the requirement in many countries to obtain marketing approval for pharmaceutical products from a health ministry. In respect of preventing others from using the invention, the patentee is limited to the scope of the “claim” contained in the patent. The “claim” is a formal part of the patent which clearly indicates the scope of the patent. It is the “claim” against which the patentability of an invention is judged and against which infringement by others of the patent is determined.

The exercise of the right to exclude others from using a patented invention may be subject to limitations in some countries, including by the right of the government to use the invention or by the grant of compulsory licenses. Moreover, countries may put in place legislation that specifies practices in the licensing of patents that have an anti-competitive effect.

A patent system, to function properly, should be balanced. On the one hand, the patentee must be granted effective protection for his or her invention to induce further research and encourage the disclosure of inventions to the public. On the other hand, national law may take cognizance of the constraints that may be imposed on the grant and exercise of the patent right.



## 3. World Trade Organization (WTO)

### 3.1 Pharmaceutical Patents and the TRIPS Agreement – Speaker: Adrian Otten

The purpose of this note is to describe those provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that relate to the standards of patent protection to be accorded to inventions in the area of pharmaceuticals. To set this discussion in context, it is useful to recall three basic features of the TRIPS Agreement:

- that, together with some 25 other legal texts, it is an integral part of the Agreement Establishing the World Trade Organization (and therefore subject to the WTO dispute settlement system);
- that it covers not only patents but all the other main areas of intellectual property rights; and
- that it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

#### What pharmaceutical inventions must be patentable under the TRIPS Agreement?

The main rule relating to patentability is that patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability – namely, novelty, inventive step and industrial applicability. In addition, Members are required to make grant of a patent dependent on adequate disclosure of the invention and may require information on the best mode for carrying it out. Disclosure is a key part of the social contract that the grant of a patent constitutes since it makes publicly available important technical information which may be of use to others in advancing technology in the area, even during the patent term, and ensures that, after the expiry of the patent term, the invention truly falls into the public domain because others have the necessary information to carry it out.

Three types of exception to the above rule on patentable subject-matter are allowed. These may be of interest from a public health perspective:

- inventions the prevention of whose commercial exploitation is necessary to protect “*ordre public*” or morality, including to protect animal or plant life or health;

- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.

### **What are the rights conferred by a patent under the TRIPS Agreement?**

The minimum rights that must be conferred by a patent under the TRIPS Agreement follow closely those that were to be found in most patents laws, namely the right for the patent owner to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process.

#### **Term of protection**

Under the TRIPS Agreement, the term of protection must be at least 20 years from the date of filing the patent application. It should be noted that, although the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the negotiations, the TRIPS Agreement does not contain an obligation to introduce such a system.

#### **Limitations/exceptions to these rights**

Under the TRIPS Agreement, patent rights are not absolute but can be subject to limitations or exceptions. These can be put into three categories:

- the Agreement allows limited exceptions to be made by Members provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interest of third parties. Thus, for example, many countries allow third parties to use a patented invention for research purposes where the aim is to understand more fully the invention as a basis for advancing science and technology;
- the Agreement also allows Members to authorize use by third parties (compulsory licences) or for public non-commercial purposes (government use) without the authorization of the patent owner. Unlike what was sought by some countries in the negotiations, the grounds on which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner. There is not space to discuss all of these here, but two of the main such conditions are that, as a general rule, an effort must first have been made to obtain a voluntary licence on reasonable commercial terms and conditions and that the remuneration paid to the right holder shall be adequate in the circumstances of each case, taking into account the economic value of the licence;
- the Agreement recognizes the right of Members to take measures, consistent with its provisions, against anti-competitive practices and provides more flexible conditions for the grant of compulsory licences where a practice has been determined after due process of law to be anti-competitive. For example, each of the conditions specifically referred to

above for the grant of compulsory licences may be relaxed in these circumstances. The Agreement also provides for consultation and cooperation between Members in taking action against anti-competitive practices.

### Transition provisions

The TRIPS Agreement lays down some rather complicated transition provisions which give countries periods of time in order to adapt their legislation and practices to their TRIPS obligations, which periods differ according to the type of obligation in question and the stage of development of the country concerned. Here we will limit the discussion to those transition provisions which relate to the application of the obligations on substantive standards for the protection of pharmaceutical inventions. For these purposes, the obligations should be divided into two categories:

- (i) the obligations relating to the introduction of product patent protection for pharmaceutical products in those developing and least developed countries which do not yet grant it. Since most developing and least developed country Members of the WTO already provide for product patent protection for pharmaceuticals, a relatively small number of countries are concerned;
- (ii) obligations regarding process patents for this group of countries and all patent protection obligations for other developing and least developed countries.

With respect to the second category above, the basic rule is that developing and least developed countries have until 1 January 2000 and 1 January 2006, respectively, to meet the obligations in question. At that time, the rules of the TRIPS Agreement will apply not only to new patent applications but also to patents still under protection in their territories.

With respect to the first category of situations referred to above, the developing countries in question have until 1 January 2005 to apply product patent protection to pharmaceutical products and the least developed countries until 1 January 2006. Notwithstanding proposals to the contrary, the TRIPS Agreement does not require the bringing under protection of pharmaceutical inventions that were in the "pipeline" in these countries at the time of entry into force of the WTO. However, with effect from the entry into force of the WTO (1 January 1995), these countries have been under an obligation to provide a system whereby applications for patents for pharmaceutical product inventions can be filed (often referred to as a "mailbox" system). These applications do not have to be examined until after 1 January 2005 (or 1 January 2006 in the case of least developed countries). If found to be patentable by reference to their filing (or priority) date, a patent would have to be granted for the remainder of the patent term counted from the date of filing. In the event that a pharmaceutical product that is the subject of a "mailbox" application obtains marketing approval prior to the decision on the grant of a patent, an exclusive marketing right of up to five years will have to be granted provided that certain conditions are met.

### Concluding remarks

It will be noted that most developing and least developed countries already grant patent protection for pharmaceutical products. In these countries, the TRIPS Agreement will therefore not lead to fundamental changes in this regard, although a certain amount of adjustment in legislation, for example in respect of patent term and compulsory licensing, may be necessary. With respect to the fairly limited number of countries that did not provide patent protection for pharmaceutical products at the time of entry into force of the WTO Agreement, some, including Brazil and Argentina, have decided to bring such protection into effect more quickly than is required under the TRIPS Agreement.

It will also be noted that the TRIPS Agreement pays considerable attention to the need to find an appropriate balance between the interests of rights holders and users and that this was an important theme in the negotiations. This is not only reflected in the basic underlying balance related to disclosure and providing an incentive for R&D, but also in the limitations and exceptions to rights that are permitted and in the transition provisions.

It should also be appreciated that the protection of pharmaceutical inventions is one aspect of a much wider agreement, covering not only the protection of intellectual property in general in a coherent and non-discriminatory way but also further liberalization and strengthening of the multilateral trading system as a whole. While it is true that some countries put particular emphasis on TRIPS matters in the Uruguay Round negotiations, it is also true that other countries attached great importance to other areas, for example textiles and agriculture. It is our belief, and a belief shared by all WTO Members, that a strong and vibrant multilateral trading system is essential for creating conditions for economic growth and development worldwide. This in turn provides for the generation of the resources required to tackle health problems.

## 3.2 Overview of the WTO Agreement on Technical Barriers to Trade – Speaker: Doaa Abdel Motaal

### Overview

The WTO Agreement on Technical Barriers to Trade (TBT) entered into force in 1995, with the establishment of the WTO itself. It was developed in response to the rise of non-tariff barriers to trade, and addresses product technical requirements and conformity assessment procedures.

The TBT Agreement is premised on an acknowledgement of the right of WTO Members to develop technical requirements and conformity assessment procedures. However, it has as its objective ensuring that unnecessary obstacles to international trade are not created. This is achieved through a delineation of a number of legitimate objectives for which mandatory technical requirements may be developed, and through a number of principles which govern the preparation, adoption and application of mandatory and voluntary requirements and conformity assessment procedures, such as: non-discrimination, the avoidance of unnecessary obstacles to international trade, harmonization, the equivalence of technical regulations, mutual recognition, and transparency. The scope of the Agreement extends to central and local governmental standardizing bodies, as

well as to non-governmental ones. A more detailed presentation of the Agreement is provided in the following sections.

## Coverage and Definitions

The TBT Agreement divides technical requirements into two categories: technical regulations and standards. According to the Agreement, a technical regulation is a:

*"Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."*

On the other hand, a standard is a:

*"Document approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."*

The main difference between technical regulations and standards is that compliance with technical regulations is mandatory, while compliance with standards is voluntary. While technical regulations are addressed through the main body of the Agreement, standards are addressed separately through a Code of Good Practice contained in an annex to the Agreement. Many of the principles applied by the Agreement to technical regulations apply to standards through the Code. However, the Code is open to acceptance by all central, local, and non-governmental standardizing bodies falling within the territory of a WTO Member, as well as to regional ones.

The Agreement also applies to conformity assessment procedures, and defines these as:

*"Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled."*

## Legitimate Objectives

Under the Agreement, technical regulations may only be developed for one or more of the objectives considered 'legitimate' by the Agreement. Legitimate objectives include: *"inter alia, national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment."* The risks associated with legitimate objectives are assessed against a number of factors, including: *"inter alia, available scientific and technical information, related processing technology or intended end-uses of products."*

## Non-discrimination

The principle of non-discrimination constitutes the backbone of the international trading system. In general, it is a principle which outlaws discrimination amongst the products of WTO Members, and between imported and domestically produced products. According to GATT Article I, the "Most-Favoured-Nation" (MFN) clause, WTO Members are bound to grant to the products of other Members treatment no less favourable than that accorded to the products of any other country. Thus, no country is to give special trading advantage to another, or to discriminate against it. According to GATT Article III, the "National Treatment" (NT) clause, Members must treat imported products no less favourably than domestically produced products. The TBT Agreement embraces the GATT principle of non-discrimination. It states that technical regulations, standards and conformity assessment procedures must be prepared, adopted and applied non-discriminatorily.

## Avoidance of Unnecessary Obstacles to International Trade

The avoidance of unnecessary obstacles to international trade is the principal objective of the TBT Agreement. The Agreement states that technical regulations, standards and conformity assessment procedures must not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to trade. Technical regulations and conformity assessment procedures must not be more trade restrictive than necessary to fulfil a legitimate objective, taking into account the risks that non-fulfilment or non-conformity would create.

## Harmonization

The TBT Agreement encourages WTO Members to base their technical regulations, standards, and conformity assessment procedures on international standards, guides and recommendations, when these exist or their completion is imminent, except when they are deemed to be inappropriate or ineffective. The call for harmonization is designed to avoid the emergence of undue layers of technical requirements and assessment procedures, and to encourage the use of ones developed by the international community. To complement this requirement, the Agreement calls upon Members to participate in the work of international standardizing and conformity assessment bodies. It recognizes that there may be instances in which Members would need to derogate from the obligation to harmonize, and, for certain specific instances, allows them to do so.

## Equivalence and Mutual Recognition

The TBT Agreement calls upon Members to recognize other Members' technical regulations as equivalent to their own, even when they differ from theirs, provided they are satisfied that they adequately fulfil their objectives. As international harmonization is a time-consuming process, and is sometimes one which is difficult to achieve, the Agreement encourages Members to accept each other's regulations as equivalent until full-fledged international harmonization becomes possible. With respect to conformity assessment procedures, the Agreement calls upon Members to enter into mutual recognition agreements for the acceptance of each other's assessment results. The purpose of this provision is to avoid multiple product testing and its associated costs.

## Transparency

Transparency is a central feature of the TBT Agreement, and is comprised of: notification obligations, the establishment of enquiry points, and the creation of the WTO TBT Committee. Notification means the circulation of information by a WTO Member to other Members on matters relating to the Agreement. Notification obligations include: notifying the measures taken to implement the provisions of the TBT Agreement nationally (such as how its provisions have been incorporated into domestic legislation); notifying draft technical regulations, conformity assessment procedures and standards, and providing other Members with sufficient time to comment on them (with the obligation of taking these comments into account); and, notifying entry into any bilateral or multilateral agreements regarding technical regulations, standards or conformity assessment procedures.

The TBT Agreement stipulates that each WTO Member must establish an enquiry point that can respond to questions on technical regulations, standards and conformity assessment procedures (whether proposed or adopted), and supply relevant documents. The Agreement has also established a TBT Committee in the WTO, which is a standing body that acts as a forum for consultations on all issues pertaining to the Agreement. Participation in the Committee is open to all WTO Members.

## Developing Countries

Under the TBT Agreement special and differential treatment for developing countries is authorized, and developed countries are encouraged to provide developing countries with technical assistance on matters pertaining to the Agreement.



## 4. South Centre - Speaker: Carlos Correa

### *Trade Agreements on Intellectual Property and Public Health in Developing Countries*

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPs Agreement") contains a number of provisions that are likely to affect access to medicines in developing countries. This is particularly the case in countries under the obligation to introduce patent protection for pharmaceuticals. But the effects may be also felt in countries that recognized such patents before.

The TRIPs Agreement, in effect, includes several provisions that are bound to strengthen the protection conferred on pharmaceutical product and processes, such as the provisions relating to:

- the duration of patent protection (minimum of 20 years from the application date);
- extension of the protection to the products directly obtained by a protected process;
- reversal of the burden of proof in the case of civil procedures relating to process patents;
- protection of confidential data submitted in applications for the approval of pharmaceuticals.

It should be noted that the TRIPs Agreement does not constitute a **uniform law**, and that WTO Member countries have some flexibility in their implementation of the Agreement's provisions at the national level. Article 8 makes a specific reference to the protection of "public health" as one of the elements to be considered while formulating or amending national laws in conformity with the provisions of the Agreement. In addition, article 27 contains two health-related possible exceptions to patentability: "*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ... health...*". They may also exclude diagnostic, therapeutic and surgical methods for the treatment of humans (article 27.3.a).

Likewise, under article 30, Member countries may provide several exceptions (such as the so-called "Bolar exception"), and under article 31 may establish compulsory licenses, including for health-related grounds. Parallel imports may be also admitted on the basis of the principle of exhaustion of rights (article 6).

The possible effects of the changes in pharmaceutical patent protection in the health sector may be seen from different perspectives. The likely impact of the new rules on the prices of medicines has been addressed by a number of studies, undertaken before and after the adoption of the TRIPs Agreement.

For instance, in the pre-TRIPs period, Nogués (a World Bank economist) estimated consumer misallocation in developing countries and found that the introduction of pharmaceutical patents would entail significant welfare losses for consumers and income gains to patent owners.

After the adoption of the TRIPs Agreement, Subramanian (an IMF economist) examined the likely impact of introducing pharmaceutical product patents in small and large countries, in cases where either a perfectly competitive market or a Nash-Cournot duopolistic market becomes a monopoly under patents. The same author later applied this model to the particular case of Asian countries (India, Indonesia, Pakistan, Philippines and Thailand). He investigated annual price, welfare and profit effects for these countries consequent upon the TRIPs Agreement. Welfare and price effects were found to be negative for these countries, though given the transitional periods provided for by the Agreement and the extensive time required for the approval of new medicines, the effects would not be felt immediately. The same methodology, when applied to Argentina, also indicated a significant price increase (71%) and a fall in consumption (50%) when monopoly follows a competitive situation, and 16% and 25%, respectively, in the duopolistic-monopoly scenario.

There are several methodological problems for estimating the likely impact of changes in patent law on pharmaceuticals as a result of the implementation of the TRIPs Agreement since - among other reasons - there are important differences from country to country in respect of patent laws, the characteristics of the local pharmaceutical industry, income levels and patterns of consumption. In addition, it is difficult to estimate the market share that would be covered by patented products, and estimates on price increases and welfare effects require assumptions on price elasticity for which only scant evidence is available.

Though the results of the various studies undertaken on possible price increases for medicines vary significantly, there is no doubt that patents lead to prices higher than those prevailing without protection. The generation of monopolistic rents is, in fact, the very purpose and essence of the patent system. Hence, while introducing or strengthening patent protection, in conformity with the TRIPs Agreement, its possible social effects, particularly on the low-income population, should be explicitly and carefully considered.

Finally, from a public policy perspective, the possible effects of changes in patent protection on other aspects, such as local innovation, foreign direct investment and transfer of technology, should also be assessed. So far, the available evidence indicates that, in general, a reinforced and expanded protection is not likely to increase the local rate of pharmaceutical Research & Development nor the flows of technology and investments to developing countries.

## 5. Health Action International (HAI)

### Speaker: Zafar Mirza

#### *Globalization and Pharmaceuticals: Implications for Public Health Policy Perspectives*

Health Action International (HAI) believes that global trade liberalization (globalization) can and does have negative impacts on public health, especially in developing countries. Globalization is promoted and protected by a range of international trade agreements, most notably the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) being implemented under the World Trade Organization (WTO). Most, if not all, countries are expected to join the WTO in the coming years. The adoption of the GATT Trade-Related Aspects of Intellectual Property (TRIPS) Agreement has significant implications for pharmaceuticals.

Certainly, the commercial interests of pharmaceutical corporations can complement public health goals. But just as importantly, they can conflict. HAI believes that national governments must maintain the ability to regulate trade in the public interest. HAI also believes that WHO has an important role in assisting countries to comply with trade agreements, while protecting public health, and in having a regular role in providing health expertise to the WTO, particularly in the settlement of trade disputes.

#### **HAI's Public Health Principles Concerning Intellectual Property Protection:**

- IPP is granted for developing a product or process to provide incentives to make that product or processes available to the public.
- A patent is not an absolute right nor an end in itself; public health is an end in itself.
- IPP for pharmaceuticals should always promote and be consistent with public health goals.

Public health goals and commercial interests of companies sometimes coincide and sometimes diverge. They are not identical. When they conflict, governments should always have the ability to choose public health as a legitimate reason for limiting or conditioning commercial interests and rights.

#### **Public Health Implications of Trade Agreements**

##### Patents that lead to higher drug prices restricts access

Patent protection increases the likelihood that prices for a patented product will be higher, especially if competition is limited. Price data also suggest that pharmaceutical corporations are often setting prices according to what the market can bear, not in order to recoup reasonable development costs and profits. Finally, pricing data clearly show that prices of a patented drug drop quickly and dramatically (30 percent) when the patent expires and a generic

equivalent comes onto the market. Moreover, price is an important determinant in access to necessary drugs. Whenever patents allow companies to price any drug out of the reach of those who need it, public health suffers.

Trade agreements do not promote R&D on diseases prevalent in developing countries

One of the main arguments for strong patents is that they are necessary for R&D. However, 75 percent of the world's population in developing countries consume only 14 percent of the world's drug supply. Fifteen percent of the population in industrialized countries consume 86 percent. Free trade policies and trade agreements are not addressing the obvious market failure to develop and market affordable drugs for diseases most prevalent in poorer regions, such as TB, malaria and HIV/AIDS.

Trade agreements reinforce justifications for commercial secrecy to the detriment of transparency and drug regulation

The positive connection between rational drug use and public health is clear, as is the connection between access to adequate drug information and rational drug use. Therefore, it is disturbing to note that TRIPS has been used recently to argue that access to the full clinical trial data would breach the intellectual property rights of an applicant for a marketing license in Europe.

### **Strategies for Complying with Trade Agreements while Protecting the Public**

In debates on trade and public health, it is very important not to lose sight of the following realities: (1) countries do have alternatives in how they choose to comply with them; (2) they have the right to pursue them in their best interests, which may conflict with other countries' or corporations' interests without being illegal under the WTO; and (3) the WHO has a mandate to provide member states with technical assistance, information and advice in how best to protect and promote health for all, which includes addressing the public health implications of trade policies, legislation, regulations and agreements.

Furthermore, the WTO is only three years old. Countries are still in the process of joining, including many developing countries. Countries should have impartial technical advice about coming into WTO compliance with TRIPS. The number of disputes involving public health issues is still limited. In such cases, the WTO needs to have impartial advice from public health experts.

### Recommendations at the National Level

*Develop effective national drug policies and promote the adoption of essential drug lists*

A noteworthy study of international drug pricing done in the 1980s showed that the presence of successful national drug policies was a major factor in lowering drug prices. Furthermore, countries that adopt essential drug lists will have a mechanism for determining what drugs are needed according to the disease patterns in their own countries and can base approvals and/or government procurement based on need, efficacy and price.

*Use compulsory licenses to achieve public health goals*

Under TRIPS, member countries have the right to issue compulsory licenses on patents based on various public interest grounds (e.g., making essential drugs available at lower cost), subject to several safeguards and limitations.

*Permit parallel imports of pharmaceuticals*

Global free trade should include the right to shop globally for the best prices. Parallel imports are particularly important for smaller economies that suffer from inadequate competition. Where allowed, parallel imports have shown to be effective in lowering drug prices. A study of the price of HIV drugs in the United Kingdom shows that parallel imports offer an average saving of 41 percent from the list price and a 30 percent saving from the best contract price.

*Ensure that trademark protection does not interfere with public health policies*

Protection of trademark rights should not interfere with sound public health policies to promote the greater use of generic drugs or to regulate marketing. It should be clear that countries can require generic drug substitution, substitution by generic name or the printing of the generic name on the packaging of the product.

*Promote the production and use of generic drugs*

Bioequivalence testing, allowed close to the expiration of a patented drug (e.g. six months), does not violate a patent. Preventing testing until the end of the patent has the same effect as granting an extension on that patent by forcing a delay in introducing a generic, which means extended higher prices for consumers.

*Promote access to drug information*

IPP in national legislation or through international trade agreements should not be used to unjustifiably maintain corporate control over drug information. Specifically, access to clinical trial data is necessary for the public and health care professionals to make rational decisions about drugs.

*Focus on alternatives that promote R&D for drugs needed locally*

Patents are not the only means for promoting R&D nor do they ensure that needed drugs are brought to market. Trade agreements must be negotiated and interpreted in ways that will permit the adequate redress of that market failure.

Recommendations for WHO*Promote WHO input into understanding TRIPS and other trade agreements*

WHO, as a UN agency, is well placed to be an honest broker in offering guidance, information and advice to member states on how to best protect public health while implementing trade agreements. For example, WHO/DAP has produced a clear and informative document entitled Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement (WHO/DAP/98.9), which gives useful guidance for implementing WTO obligations. The document should be made widely available.

*Secure a regular role in providing expertise in WTO trade disputes*

WTO panels are comprised of trade experts that can and should benefit from WHO opinion on issues of public health. A few years ago, the United States challenged Thailand's import restriction and a strict tobacco advertising ban. In

weighing its decision, the WTO relied heavily on submissions from the WHO and on WHA resolutions.

### **Conclusion: Public Health First**

National governments have a vital role to play in ensuring the protection and promotion of public health. Although trade agreements limit how they can regulate trade, governments retain a range of alternatives they can pursue to maximize public health goals in a globalized economy. WHO is well placed to advise member states in these matters. Likewise, WHO is well placed to provide expertise to the WTO, particularly in the settlement of disputes involving health issues.

## 6. International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

### Speaker: Harvey E. Bale

#### *Globalization: pharmaceuticals and vaccines*

*“Everything that can be invented has been invented.”*  
Charles H. Duell, US Patent Commissioner, 1899

*“We can close the book on infectious disease.”*  
William Stuart, US Surgeon General, 1969

Thank you Mr. Chairman, other Working Group members and the WHO for this opportunity to present the perspective of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). IFPMA represents over 55 national industry associations from both developed and developing countries. Companies in membership of IFPMA are the major global research-based pharmaceutical and vaccine companies; but they are also companies which produce a very large volume and value of both generic medicines and non-prescription drugs. In the current research and development pipeline, our industry has over 100 medicines and vaccines for infectious diseases in addition to more than 100 HIV/AIDS related-medicines; over 300 medicines for cancer; more than 90 for heart disease and stroke; and in excess of 300 medicines for diseases that disproportionately affect women.

Innovation leading to new medicines is of crucial importance for meeting public health challenges in both developed and developing countries. Innovation is not a luxury for rich countries but a necessity to fight disease, including where emerging diseases or anti-microbial resistance are present. By permanently bringing to the market new drugs for unmet medical needs, the research-based pharmaceutical industry contributes to enhancing public health throughout the world, including countries where tropical diseases are a special problem.

Globalization has been defined by a Dutch expert on the subject as an “acceleration of something becoming worldwide such that it gives rise to many new phenomena.” One of the most profound effects of globalization insofar as pharmaceuticals are concerned is more research will be done more on a *global basis* than is the case today - as a result of recent international agreements, particularly the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS). There is important evidence that this is already happening. In developing countries, local companies are beginning to respond to the new order and are increasing their efforts to find new medicines. For example, in Korea, where patent protection for drugs was introduced ten years ago, a local Korean company executive has written me to say that *Korean* companies, after overcoming the initial challenges of new patent laws are increasing their drug

research budgets and increasing rapidly their patent applications. And in India where infectious diseases are a serious social burden, according to *local* industry association reports, *Indian* companies are responsible for most of the increase in pharmaceutical patent filings last year. Indian society and the world will be much better off over the longer term because TRIPS, the WTO agreement on intellectual property protection is encouraging local companies to shift from copying to invention. There is also the positive effect on local production that can come from outside investment. Mexico and Brazil, which recently enacted strong patent protection and provided exclusivity to products in the development pipeline, have seen a rapid rise of investment in its country's pharmaceutical sector, especially from international companies. Some of the changes in developing countries' laws are too recent to show data on local investment in research and production, but the experience gleaned years ago from Spain, Italy, Japan and Canada, all of whom have refined and upgraded their pharmaceutical patent laws shows that local producers do not suffer greatly at the same time that increases occur in local research and development. So the experience from both developed and developing countries is positive.

However, while the threat and burden of many diseases has been global, pharmaceutical research efforts have been until now concentrated in relatively few countries. In the future, TRIPS rules can be expected to spread the application of research more globally and involve *local* companies and countries which have not been part of the effort to discover new treatments, cures and preventive vaccines. Also, *international* companies can be expected to increase investment and partnerships with locally-oriented companies, where the lack of patent protection and the prevalence of counterfeiting has hindered such activities until now.

The majority of new medicines are discovered, and nearly all such medicines and vaccines, are developed by commercial industry. Industry undertakes the risks of doing multi-year tests on the effective dose, proper indications, and safety profiles of new chemical and biological compounds, and then designs quality assurance systems for manufacture of the medicines - all of this before the medicine is approved (or rejected) by governmental regulatory authorities. The failure rate is high: only 1 medicine receives marketing approval out of more than thousands of compounds screened for therapeutic benefit, and only one medicine out of five entering clinical trials is approved for patient use. Given this and the fact that it takes on average ten years from discovery of a compound to delivery to patients, the drug research and development process is not only risky but it is also expensive. In *developed* countries the average cost of a new drug today is in the neighbourhood of \$500 million. (This means that developing countries, where costs of clinical trials can be less costly, could be attractive for pharmaceutical technology transfer.) It should be added that only a minority of new drugs are profitable and repay their costs, though it is typically impossible to know whether a given compound will be successful 5 to 10 years before it reaches patients around the world. Thus strong intellectual property protection in major developed and developing countries is absolutely essential.

Because many drugs are relatively inexpensive to copy, and counterfeiting is even carried out more cheaply, it is important that strong intellectual property rights apply to pharmaceuticals and vaccines in the important markets in both developed *and* developing countries. The TRIPS agreement goes far to assure that new medicines will be forthcoming to patients in both developed and

developing countries. Patient access to effective therapies is lacking today in countless disease categories, and new diseases are constantly appearing (twenty or so over the past two decades) while resistance to drugs for older diseases such as malaria and tuberculosis is rising. Stronger worldwide patent, trademark and trade secret protection promise to increase access to new therapies to address what are considered incurable diseases today.

What about access to medicines? Will these international agreements have an adverse effect on access to essential medicines? First it can be firmly stated that "access to medicines" is not a one dimensional issue related to price, but is far more complex. Researchers from India recently published a paper entitled "Drug Utilization Patterns in the Third World" and have pointed out that there are many factors affecting access to medicines, including poor management and coordination, misuse of self-medication, low level of public expenditure on health care, lack of basic infrastructure, inadequately trained personnel and poor allocation of financial resources (e.g., between rural and urban areas), including drugs and vaccines, and the lack of adequate health care infrastructure. There are many inexpensive generics on the market today, which raises a question: even if drugs were given away free, how far would this go to solve the access problem? Probably not very far. I wonder if there is not something that we can do to make a difference though. What if WHO and IFPMA were to examine together some of the key issues affecting drug distribution, reducing wastage and improving quality control in least-developed countries, and then exploring how we can work together to improve access?

Secondly, on the question of the effect of new international agreements on the local prices of pharmaceuticals, no generalization can ever apply to *every* specific situation. However, it can be stated that potential concerns are often not matched by reality. Regarding price effect of patent changes, there is empirical evidence based on actual market studies of the data that it is almost nil or insignificant. This is for a number of reasons. First, patents are not retroactive in effect, thus any product legally on the market at the time that a patent law comes into force is totally unaffected. The important point here is that generic drugs are always available and do exist side-by-side patented products. I am acutely aware of this because many companies in IFPMA are also major generic producers. Also, there is growing competition within therapeutic classes. As the technology improves, there is less real exclusivity in therapeutic clusters, as evidenced most recently with the appearance of multiple patented HIV/AIDS drugs within months of each other. Again, other factors usually have a greater impact on prices including the market structure, existence of distribution bottlenecks and artificial distribution margins, regulatory and tax conditions, inflation, exchange rates and the pattern of drug consumption in various countries.

Thirdly, to indicate that prices are not associated with patent law changes, one need only observe the irony that in some countries which do *not* have patent protection, the prices of copies are often *higher* than the prices of the originals. Thus weak or non-existent patent protection is not "consumer-friendly", and consumers often pay twice - in the lack of reinvestment of profits of copying firms in new drugs and in the often-inflated price of illegitimate copies.

Fourthly, patents do not create 20 year "monopolies". Instead, companies face old and new competition in therapeutic categories. And companies also have far fewer than 20 years to exploit their patents. People who understand the

industry know that the life of a patent begins to expire long before a pharmaceutical product reaches the patient. This is why Europe, Japan, the United States and Australia have increased the patent life beyond twenty years. But developing countries are not required by TRIPS to do the same.

Finally, beyond these facts, individual companies with new patented products created as a result of the patent system often enter into discussions with WHO and governments to provide donations and other programs to assist in specialized problem categories - recent examples being initiatives with UNAIDS and with onchocerciasis, filariasis and trachoma. On the other hand, companies with an inclination for research into drugs for diseases of the Third World have *much less* incentive to dedicate themselves to such programs if medicines are *internationally diverted* through parallel trade - which is a windfall benefit for traders but a hidden tax on poor countries as well as a regulatory nightmare, risking the introduction of substandard and counterfeit medicines into the drug chain.

With regard to the impact of changes in intellectual property laws on local companies, in addition to the benefits to be expected from increased research at a local level, evidence from the experience of developed and developing countries which have adopted stronger patent protection over the past decade indicates that local industry is *not* made redundant. On the other hand, a strong local or international generic company needs good manufacturing quality assurance programs and the flow of new products coming from strong patent protection in order to survive and grow. The fact is that local industry - and patients - need to be focused more on improving GMPs and quality standards in this new global environment than patent protection because patient safety and global competition dictate higher standards. IFPMA and its members are always prepared to work with WHO and its member states to improve quality standards of pharmaceuticals worldwide. This year we sponsored a seminar on regulatory issues in Hong Kong, involving officials from that region and we will do another one next spring in Singapore.

In conclusion, I raise some questions that we must consider. In 1899, the US commissioner of patents stated that the Patent Office should be *closed* because, he said, "Everything that can be invented has been invented". Equally inaccurate was the US Surgeon General who in 1969 testified before Congress that "We can close the book on infectious disease". As the Danish physicist Niels Bohr once remarked, "Prediction is very difficult - especially about the future". What about the future, namely of disease and of patents and inventions to fight such disease?

Do we think that there is nothing more to be discovered and developed in the fight against malaria, TB, cancer and AIDS? Do we think that we can close the book on infectious disease? Are we in the fight against disease together for the long-term? Are commercial companies - which have combined science with development expertise to produce drugs for many tropical diseases - partners in public health? If so then we had better recognize that our companies' contributions through discovery and invention can only be fostered by avoiding threats to the emerging institutions of patent and trademark protections that will be gradually coming into force over the coming decade through international agreements. There are no winners in a game whose goal is to find loopholes in this protection - except those who would drain society of opportunities and skills by copying rather than inventing. The patent system, as the US President

Abraham Lincoln once said, has “added the fuel of interest to the fire of genius”. It is the intellectual property system that will increasingly and globally harness *more genius* to the struggle against disease.

Both the *development* of and *access* to medicines is a real issue in today’s global environment. Neither are served by interfering with intellectual property rights. What is needed instead is a long-term global partnership: WHO, industry, national governments and international funding agencies, the WTO and WIPO. All can play complementary roles in doing research and development work, strictly enforcing patent and other intellectual property laws, providing adequate funding in countries which lack adequate resources and improving access through the improvement of local infrastructure.

In conclusion, I thank the Working Group for permitting IFPMA to present the perspective of an industry that in this year will spend over \$40 billion in research and development in the search for new cures for old and newly emerging disease. We hope that this dialogue might continue in the coming years. Without decisions being based on dialogue, the commercial industry’s ability to serve public health, and public health itself, will undoubtedly suffer.



## 7. International Generic Pharmaceutical Alliance (IGPA)

### Speaker: Greg Perry

#### *Globalization of Pharmaceuticals - Effects of Trade Agreements on Intellectual Property and Public Health*

##### **Introduction – IGPA**

On behalf of the International Generic Pharmaceutical Alliance, I would like to thank the WHO for the invitation to speak today.

As you can see from our short position paper, IGPA is a recently formed industry association. The creation of our group is one example of the changing nature of the global pharmaceutical sector.

It should be noted that in advanced countries generics can account for up to 60% of markets. For developing countries generics are critical to their Essential Drugs Policy.

##### **“Balance” in TRIPs**

Today I want to address the issue of intellectual property rights and TRIPs and the relationship to health policy. I believe that IP issues, particularly in the health sector, should be regarded on a basis of “balance” of interests. For this reason I was very happy to hear that Mr Otten stated that TRIPs incorporates “balance” and “third party interests”. This “balance” is one of two pillars of the TRIPs Agreement. Professor Correa enlarged upon this by identifying certain areas that are possible for protecting essential drug policy within TRIPs. I would like to expand on this and discuss the issue of balance in some detail.

As a starting point I want to make it clear that we do not challenge the basic equation of increased patent protection in TRIPs equals increased revenues and security for research and development which equals increased innovation which equals an improvement in health policy. This has been agreed in principle by most countries in the world through the signing of TRIPs. What we do need to discuss is how this relates to ensuring access to innovation and affordability of pharmaceutical care in general. The debate therefore needs to look at price and profit as well. Most importantly we need to look at the options of “balance” written into TRIPs.

##### **IP and Pharmaceutical Markets**

I think it is important to remind ourselves of some general principles on IP law. These are that:

- i) protection is limited in time;

- ii) knowledge must eventually come into the public domain;
- iii) competition must not be stifled in the long term.

These principles are applicable to the pharmaceutical sector as they are to any other.

As regards the market, the pharmaceutical sector does have some important characteristics which we must also consider. These are:

- The buyer is not the one who decides - the decision is the responsibility of the doctor. This is important when you consider that patients are increasingly paying the cost of medicines. We have heard today that 90% of those in the developing world pay their own medical bills.
- Governments have a special role because they are usually responsible for people's health and, in many situations in the western world, responsible for paying the costs. Therefore we cannot talk about the free market.
- Registration of a new product does take time. But it should be stressed that time-periods are not 10-12 years, as is often claimed, but rather 5-8 years. There has been, for example, a significant reduction in registration times in the EU.
- Investment costs of innovation are relatively high but profit margins/returns on innovation are, equally, very high.

The potential for competition and a low price for products comes mainly in the off-patent sector.

### **The Contribution of Generics**

It is the aspect of the generics sector which I would now like to turn to. The promotion of a generics sector is, I believe, a critical part of the "balance" in this discussion. A healthy generic sector has the following contributions:

**Stimulates competition** - If a company had a permanent monopoly on a product it would have little incentive to look for new innovative products.

**Reduces prices and makes access to medicines a reality** - Despite what we may have heard today, generics are sold on average at prices of 20-80% of the original price in most advanced countries.

**Provides "headroom for innovation"** - Simply put, buying generics allows health budgets or personal budgets the capacity to buy more expensive drugs when actually required.

**Provides wealth creating small companies which can grow and eventually invest into research and development.**

**Most significantly for developing countries, it provides the opportunity for the creation of a domestic pharmaceutical industry which will bring economic rewards and reduce economic dependency on advanced countries.** "Making

copies" is in fact much more an industrial reality for developing countries than research and development. These countries often do not have the capital or economies of scale for R&D and generic drugs relate more to health needs. So the development of local generic industry should not be ridiculed. There is however a question of quality and GMP in certain countries and this I will address later.

### How to Stimulate the Generic Sector within TRIPs

The question we should now address is how is such a sector developed and what is provided for in TRIPs that enables this?

Generic prescribing, generic dispensing, proper quality control and registration are all important aspects but do not form part of the IP discussion.

In the IP discussion, what is important is providing for a balanced approach to intellectual property. I would now like to address this in relation to TRIPs, particularly as regards

- compulsory licenses;
- advanced generic registration; and
- transitional periods.

We have heard much about compulsory licenses so I will not dwell too much on the technicalities. The system does provide an important avenue for the "transfer of knowledge" from advanced countries to developing countries and could be an important avenue for ensuring greater access to products and the development of local industry. It would appear good sense to use compulsory licenses where R&D investment of multinational firms is low or non-existent, or where new patented products are not being made available or only at prices too high for the local health market to sustain and are therefore effectively not accessible for a very large part of the population.

I would now like to address the issue of advanced generic registration. This is sometimes referred to as a "Bolar" provision. In simple terms this is a provision that enables all scientific and regulatory requirements for registering a generic medicine to be made during the period of the patent. Why is this important? Because despite what we have heard, "making copies" is not so simple. Sourcing active ingredients, performing bioequivalence studies, assuring quality, putting together a dossier, establishing patient information leaflets and going through the regulatory process can average 2-3 years. Manufacturing adds on another 3 - 6 months. Consequently if no provision existed then patent protection would be extended by 2-3½ years beyond the intended period. For this reason many advanced countries with developed markets have a provision for advanced generic registrations. These include the USA, Canada, Australia, Israel and Hungary. In the EU the situation is not harmonized and is complex, with some countries allowing advanced registration under certain conditions with others allowing when there is no batch samples required. However, the European Parliament, in 1996, called for the provision of advanced generic registration to be adopted into European law, although the European Commission has failed to bring forward such legislation.

TRIPs provides for this provision in Article 30. Although not explicitly stated it is well understood that the term *taking into account interests of third parties* covers this.

Indeed the U.S. administration has made it clear on numerous occasions that the "Bolar" provision was part of the TRIPs negotiations. Moreover, its common practice among advanced countries underlines the importance of "balance" in health policy. In fact it is this very sort of provision that typifies the "balance" which is expressed in TRIPs and to which signatory countries were agreeing. Therefore it is very damaging to the spirit of TRIPs that certain interests seek to undermine this provision. We are disappointed that the EU has decided to raise the issue of Canada's "Bolar" provision because it includes a right to manufacture (but not to sell) six months in advance of patent expiry at the WTO. The aim of this provision is to ensure immediate generic competition day one after patent expiry. However, we are confident that Canada will win if this goes to a TRIPs Panel.

As regards transitional arrangements, these do not affect the majority of companies presently represented by IGPA since, as I explained, we are for the moment principally made up of European and Northern American companies. But we do recognize the importance of these transitional arrangements for developing countries and believe that they should be respected by advanced countries.

Professor Correa pointed out that even in Europe many countries had only recently developed patent provisions, as are required by TRIPs today. It is therefore logical that countries with far less advanced economies have a proper time-scale for compliance. Equally these countries must put into place requirements already asked of them by TRIPs. The spirit of "balance" must be maintained by all parties.

### **Pricing, Substitution and Parallel Imports**

I would now like to take a little time to discuss pricing, substitution, and parallel imports. Although these are not featured in TRIPs they are clearly part of the discussion of innovation and access to health.

First, I should stress that as a general principle IGPA believes that these issues should be discussed between industry (both generics and originator) and governments in a "spirit of partnership". Secondly, as part of a generic policy for stimulating competition and access in the off-patent sector generic action has to be taken to stimulate generic prescribing and dispensing. Once prescribing and/or dispensing is generic, free pricing in the generic sector can itself lead to generic competition and affordable medicines. Consequently, price controls might not be needed to stimulate competition or low price.

However, I sense that the real problem for the originator industry is not generic competition but parallel imports. It should be recalled that generic competition comes only at the end of many years of monopoly and that the originator industry, as we have heard from the IFPMA, itself benefits from the off patent sector by developing generics. Parallel imports, on the other hand, cut into profit margins during the patent period. However, for hard pressed governments

parallel imports might be the only way to access new drugs if the price of these drugs on their market is too high.

As regards TRIPs I believe that there is nothing in TRIPs that requires governments to stop parallel imports to protect the rights of the patent holder. Conversely, there appears to be nothing in TRIPs that requires governments to allow such trade on the basis that preventing it would be a barrier to trade. I would therefore like to make a suggestion that the originator industry and governments in the developing world seek a solution that is mutually beneficial. The originator industry, for its part, could agree to a) provide new products at a "subsidized price" for an agreed number of years and b) accept a series of government actions aimed at stimulating the generic sector in the off-patent area. The governments, for their part, could agree to prevent parallel importing between their countries and grant fast authorizations for new products on their markets. In this way the originator industry could generate its high income in the normal way from advanced and middle income countries but ensure access in lower income markets without the fear of parallel trade. Clearly, this is a very rough idea at present but maybe the principle could be better developed by others. It should be clear that this is not a concept that can be used within single markets such as the EU where such restrictions would be illegal. In this case industry and governments would be better placed to look at a new pricing system which would offset higher prices against a combination of profit claw-back on new products and stimulation of the off-patent sector.

I would like to suggest that if the principle of balance is re-acknowledged by all sides in this debate we may be able to take a step forward. It would require the originator industry and certain governments of developed countries to agree to uphold the measures of balance that are possible in TRIPs, i.e. compulsory licences, advanced generic registration, transitional arrangements and parallel imports. Similarly, it would require the governments of developing countries to acknowledge their obligations under TRIPs and possibly seek a solution to the threat of parallel imports that the originator industry fears so much.

### **Other options for helping access to innovation and medicines in general**

Once we have accepted the approach of balance we could then look at a series of other issues that would help stimulate access to medicines both innovative and generic. Here I would like to make some suggestions.

First, there should be a more rapid access to the market for innovative products. This could be facilitated by giving automatic marketing authorization to any product that has been approved by the FDA, EU or Japanese authorization systems. There appears to be no sense to repeat trials or to go through lengthy regulatory processes again. It would also make unnecessary any future laws for patent restoration in other countries outside the EU, USA or Japan. All sides would seem to benefit. Clearly, from a regulatory side this relates to activities being pursued through ICH.

Second, there should be a more harmonized approach to granting patents and reducing time frames and costs for inventors. I think this is an area where WIPO and WTO are best placed to co-operate with the WHO and, as we have heard, are already very active.

Third, there should be increased assistance to improving GMP, quality standard control and registration systems of developing countries particularly in the area of off-patent and essential drug products. IGPA believes that a generic product is a quality product as well as an affordable one. Simply put, an off-patent product which does not meet the requirements of quality is not a generic medicine. Consequently, quality cannot be compromised. We accept that this may not happen overnight in developing countries but governments probably with the assistance of the WHO, the FDA and the EU should make significant efforts in this direction. In the meantime, more consideration should be given by developing countries and the generic industry in advanced countries as to how generic imports could help meet the requirements of essential drug policies.

Fourthly, there needs to be some action which will help reduce distribution and costs.

Finally, there is a need for increased efforts against counterfeit products. The selling of counterfeit products results in losses of millions of dollars of revenues for originator companies. Generic products are also counterfeited resulting in loss of revenue and confidence in our sector. A major concern is the use of the internet. Government action world-wide should be used to discourage people from buying products in this way. The WHO's present actions in this field are clearly welcomed by all sides.

### Conclusion

In concluding it should be stressed that IGPA had no problem with the original Resolution for the Revised Drug Strategy. In fact we wrote to the WHO expressing our support. It appears quite normal for public health rather than commercial interest to be given primacy in pharmaceutical legislation. One would expect nothing less from an international organization whose job is the promotion of public health. Moreover, it should be noted that the protection of public health is the primary objective of EU pharmaceutical legislation. So I think there has been a lot of over-reaction to this by certain groups.

Secondly, it is totally right for the WHO to assist its members in seeing what their options are within the TRIPs Agreement. The nature of our world trade agreements is that they cut into many new areas that affect many other policy issues. However, what may have been misunderstood from the wording of the draft Resolution was that the WHO would be suggesting that governments should seek options that were not compatible with TRIPs. Maybe the new Resolution should seek to align those fears and say that the governments should "*review their options under TRIPs to safeguard access to essential drugs whilst ensuring that these options are compatible with provisions of the Treaty*".

Perhaps between then and now the secretariats of the WTO and the WHO can make progress in identifying what those options are as defined by the concept of "balance" described above. Finally, I would like to suggest that the WHO be consulted by the TRIPs Panel in all cases where there is an issue relating to health. However, maybe we should leave that to the two organizations to sort out.

I thank you for your attention.

\* \* \*

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